Testimony

Regarding Proposals Seeking to Amend the Class 1 Fluid Milk Product Definition

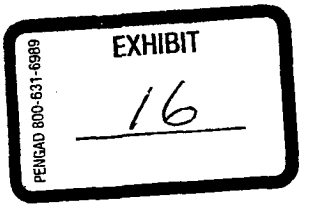
Federal Register Volume 70, Number 69

Proposed Rules Page 19012-19015

By: Gerald Carlin, Meshoppen, PA 18630

Hearing Convening on June 20, 2005, Pittsburgh, Pennsylvania

Held by: USDA/Agricultural Marketing Service/Dairy Division



Testimony presented at USDA Agricultural Marketing Service Hearing
Concerning the definition of Class 1 Milk
Gerald Carlin
June 21, 2005

Thank you for allowing me to testify today. My name is Gerald Carlin. My wife, four children and I own and operate a dairy farm in Susquehanna County, Pennsylvania. I am here today because I believe that the issues being discussed are very important. The outcome of this hearing could have a profound impact on my business, on U.S. dairy farmers in general, and on the quality and integrity of dairy products.

Of particular concern to me are a number of proposals before the Department of Agriculture, Agricultural Marketing Services, which would legitimize and allow the use of caseinates and milk protein concentrates (MPC) in Class 1 fluid milk products. Please note that MPC still does not have Generally Regarded as Safe (GRAS) status with the Food and Drug Administration (FDA) (See note #1) and is not allowed in standardized cheese even though petitions to allow its use have now been before the FDA for over five years (See note #2). In fact, in a FDA warning letter to Kraft Foods North America, Inc. dated December 18, 2002 (See note #3), Kraft Foods was found in violation of Title 21 Code of Federal Regulations, part 133 (21 CFR 133). Please note on page two paragraph one and page three paragraph three that Kraft products were "Misbranded. . . In that it purports to be or is represented as a food. . . for which a definition and standard of identity have been established." Fluid milk is held to an even higher standard than cheese.

According to an August 13, 2003 letter from Center for Food Safety and Applied Nutrition, Department of Health and Human Services, to John Bunting (See note #4), no scientific studies have been done on human safety of consuming MPC. It is a curious thing to me why after so much pressure has been applied there is still a refusal by the industry to do safety testing on MPC. Perhaps it is because there is no standard of identity for milk protein concentrate. Harmonized Tariff Schedule 0404901000 covers milk protein concentrates with protein levels of 40-90% (See note #5). Harmonized Tariff Schedule 3501101000 covers milk protein concentrates with protein levels over 90% (See note #6). Regulatory Agencies have not agreed on any standard of identity for milk protein concentrate. It is my understanding that, in general, the more a food is processed the less nutrients are digestible. Proteins are quite delicate and a change in structure could affect the way the body utilizes them.

Clearly, there is a distinction between Grade A and Grade B milk. The two are not to come in contact with each other. Equipment must be thoroughly washed and sanitized between the handling of Grade B and Grade A milk. Yet, if proposals are approved allowing MPC and Casein in Class 1 milk, Grade B product would be mixed right in with Grade A. (See note #7 for Grade A standards. Are imports held to these standards?)

In reference to inspection, a milk sample is taken from every dairy farm in

the United States every time the milk is picked up and a sample is taken from every compartment of every bulk milk truck when it is delivered to the plant. Yet, according to GAO-01-326 Ultra-Filtered Milk page nine paragraph two "Products such as milk protein concentrates, which are believed to pose minimal safety risks are frequently released automatically. FDA annually inspects or conducts laboratory analyses on less than two percent of all types of imported food shipments." (See note #8) It is a slap in the face to U.S. dairymen to allow uninspected and unregulated dairy products to be mixed in with our regulated and inspected domestic milk.

Almost all MPC and Casein are imported. These products come from many countries (See note #9). Even though there is an effort to produce MPC and casein domestically, such production is not economically feasible without subsidy (See note #10). Indeed, because we are a milk deficit nation (See note #11), where will the extra milk come from? MPC imports are increasing and casein imports remain as strong as ever. Any claim that only domestic MPC or casein would be used in fluid beverage milk would be preposterous. Domestic production of MPC or casein only serves to cloud any distinction between domestic and imported dairy proteins while giving a false impression of better quality.

I realize that the proposals to apply Class 1 price to milk proteins in fluid milk that are derived from MPC and casein give the illusion of increasing farm milk prices. Really though, who will get the money from these proteins? Will foreign producers benefit? I think it is quite clear that processors will benefit by these proposals while the dairy farmer's pay price will be eroded by diluting the Class 1 market. Not only so but milk's image could be tarnished by allowing questionable ingredients to be added and legitimizing that which is illegitimate. I strongly urge USDA to maintain its current definition for Class 1 milk.

Foot Note Documents

1. Judith L. Kidwell, Division of Petition Control, HFS-215, Center for Food Safety and Applies Nutrition, Food and Drug Administration, letter date December 29, 2000

2. National Cheese Institute (NCI) Petitions, 00P-0586-CP1 February 2000 and 00P-0586-CP2 June 2000

3. Kraft Warning Letter CHI-6-03

4. Letter from the Department of Health & Human Services, FOI Officer, Executive Operations Staff, Center for Food Safety and Applied Nutrition to John Bunting, August 13, 2003.

5. USDA Department of Agriculture, Foreign Agricultural Service, HS 10-digit Imports 0404901000

6. USDA Department of Agriculture, Foreign Agricultural Service, HS 10-digit Imports 3501101000

7. Grade "A" Pasteurized Milk Ordinance (PMO) 2001 Revision, Section 1- Section 7

8. United States General Accounting Office, Report to Congressional Requesters, March 2001, Dairy Products-Imports, Domestic Production, and Regulation of Ultra-filtered Milk GAO-01-326

9. USDA Department of Agriculture, Foreign Agricultural Service, HS 10-digit Imports 0404901000, USDA Department of Agriculture, Foreign Agricultural Service, HS 10-digit Imports 3501101000, USDA Department of Agriculture, Foreign Agricultural Service, HS 10-digit Imports 3501105000, USDA Economic Research Service, FATUS Import Aggregations, Casein and Mixtures, USDA Foreign Agricultural Service, FAS Agricultural Imports Commodity Aggregations, Casein.

10. 108th Congress 2nd Session H. R. 4223, April 27, 2004.

11. U. S. A "Milk-Deficiet Nation" Since 1996

(1)

From: Kidwell, Judith L. <Judith.Kidwell@cfsan.fda.gov>
To: <bunting@dmcom.net>
Sent: Friday, December 29, 2000 10:00 AM
Subject: Milk Protein Concentrate

This is in response to your inquiry on November 28, 2000, concerning the regulatory status of milk protein concentrate as a food ingredient.

As background, under the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, a substance that is added to food is a food additive, subject to FDA's review and approval, unless it is Generally Recognized as Safe (GRAS), by qualified experts, under the conditions of its intended use. To be lawful, a substance that is added to food on the basis of the GRAS provision must meet the criteria for GRAS status. There is no requirement that a substance that meets GRAS criteria be reviewed by FDA or listed in FDA's regulations. Because GRAS status may either be affirmed by FDA or determined independently by qualified experts, FDA's regulations do not include all GRAS ingredients. Thus, many substances, such as corn oil, are marketed on the basis of the GRAS provision without being listed in FDA's regulations.

To be responsive to industry questions about substances that are marketed based on the GRAS provisions, FDA has established two lists of GRAS substances in its regulations. In the first "GRAS list," which is codified in 21 CFR Part 182, FDA listed presumed GRAS substances that were used in food prior to 1958. In the 1970's, following a comprehensive review of the safety of presumed GRAS substances, FDA established a second list of "affirmed GRAS substances," which is codified in 21 CFR Part 184.

In 1997, FDA issued a proposed rule to replace the GRAS affirmation process with a notification procedure (Federal Register, April 17, Volume 62, Number 74). Under the GRAS notification procedure, a manufacturer who determines that the use of a substance is GRAS and chooses to notify FDA of the determination would submit a succinct description of the notified substance, including (1) the name and address of the notifier; (2) the common and usual name of the notified substance; (3) the applicable conditions of use of the notified substance (e.g., types of foods with which the substance is to be used, levels of use in such foods, the purposes for which the substance is used, and, when appropriate, a description of the population expected to consume the substance); (4) the basis for the GRAS determination (i.e., through scientific procedures or through experience based on common use in food prior to 1958); and (5) a statement that the data and information that are the basis fc the notifier's GRAS determination are available for FDA review and copying, or will be sent to FDA upon request.

Although the proposed notification procedure is not yet final, FDA has already received several notices. The agency is evaluating whether each submitted notice provides a sufficient basis for a GRAS determination and whether information in the notice or otherwise available to FDA raises issues that lead the agency to question whether use of the substance is GRAS.

In the GRAS proposal, FDA announced its intention to maintain an Inventory of GRAS Notices and the agency's response to those notices. The inventory can be found at http://vm.cfsan.fda.gov/~rdb/opa-gras.html. Importantly, the Inventory of GRAS Notices includes all GRAS notices, regardless whether the notice is pending at FDA or has come to closure, and regardless the nature of FDA's response.

Milk protein concentrate is not listed in FDA's regulations. To be lawful, milk protein concentrate must meet GRAS criteria. To be eligible for GRAS status through scientific procedures, there must be the same quantity and qua of evidence as is necessary to support the approval of the substance as a foo additive (see 21 § 170.30(b)). To be eligible for GRAS status through experi ence based on common use in food, there must be evidence of a substantial history of consumption for food use by a significant number of consumers pri to January 1, 1958 (see §§ 170.3(f) and 170.30(c)). In either case, there mu be common knowledge about the substance throughout the scientific commu knowledgeable about the safety of substances added to food (see § 170.30(

Should you need additional information or further clarification, please f free to contact us.

Judith Kidwell
Division of Petition Control, HFS-215
Center for Food Safety and Applied Nutrition
Food and Drug Administration
e-mail: JKidwell@cfsan.fda.gov

(3)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration 9374Od

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

December 18, 2002

WARNING LETTER
CHI-6-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Betsy D. Holden, President & CEO
Kraft Foods North America, Inc.
NF 301
Three Lakes Drive
Northfield, IL 60062

Dear Ms. Holden:

The Food and Drug Administration (FDA) recently conducted inspections of your facilities located in Champaign, IL; New Ulm, MN; and Springfield, MO. These inspections were conducted to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations contained in Title 21, Code of Federal Regulations, Part 133 (21 CFR 133).

Our inspectional observations and a review of certain labeling collected during the subject inspections found serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Section 133, Subpart B – Requirements for Specific Standardized Cheese and Related Products (21 CFR, Section 133, Subpart B).

Your firm's "Kraft Singles American Pasteurized Process Cheese Food," "Kraft Singles Sharp Cheddar Pasteurized Process Cheese Food," and "Kraft Singles Swiss Pasteurized Process Cheese Food" products are misbranded within the meaning of Section 403(g)(1) of the Act in that they purport to be or are represented as a food, namely pasteurized process cheese food, for which a definition and standard of identity has been prescribed in 21 CFR 133.173, and the products do not conform to the definition and standard. Milk protein concentrate is not listed in § 133.173(d) as one of the optional dairy ingredients that may be used in pasteurized process cheese food.

Your firm's "Kraft Velveeta Pasteurized Process Cheese Spread" product is misbranded within the meaning of Section 403(g)(1) of the Act in that it purports to be or is represented as a food, namely pasteurized process cheese spread, for which a definition and standard of identity has been prescribed in 21 CFR 133.179, and the product does not conform to the definition and standard. Milk protein concentrate is not listed in § 133.179(d) as one of the optional dairy ingredients that may be used in pasteurized process cheese spread.

These products declare milk protein concentrate in their ingredients listings. Milk protein concentrate (MPC) is not listed as an optional dairy ingredient in any of the standardized cheese products governed by a standard of identity, and therefore standardized cheese products are not permitted to contain MPC as an ingredient.

Further details of the inspections documenting these violations, and our observations, follow below:

- On July 8, 9, 10, 12, and 17, 2002, we conducted an inspection of your facility located in Champaign, IL. During the inspection, our Chicago District investigator witnessed the use of dry milk protein concentrate during the production of "Kraft Singles American Pasteurized Process Cheese Food." Specifically, on July 9, 2002, our investigator observed the addition of [redacted] during the manufacture of "Kraft Singles American Pasteurized Process Cheese Food." Our investigator collected labeling for this finished product, which declares milk protein concentrate in the ingredients listing.

  Product labels for "Kraft Singles Sharp Cheddar Pasteurized Process Cheese Food" and "Kraft Singles Swiss Pasteurized Process Cheese Food," both of which declare milk protein concentrate in their ingredient listings, were also collected by our investigator for review during the subject inspection.

- On July 30, 31, and August 1, 2, 2002, we conducted an inspection of your facility located in New Ulm, MN. During that inspection, our Minneapolis District investigators witnessed the use of dry milk protein concentrate during the production of "Kraft Singles American Pasteurized Process Cheese Food."

  Specifically, on July 30, 2002, our investigators observed the addition of [redacted] during the manufacture of "Kraft Singles American Pasteurized Process Cheese Food." Our investigators collected labeling for this finished product, which declares milk protein concentrate in its ingredients listing.

- On August 26, 27, 28, 29, and 30, 2002, we conducted an inspection of your facility located in Springfield, MO. During that inspection, our Kansas City District investigators witnessed the use of dry milk protein concentrate during the production of "Kraft Singles American Pasteurized Process Cheese Food." Specifically, our investigators observed the combining of [redacted] with whey, and whey protein concentrate with water, to create a batch of wet mix. The wet mix was then added during the manufacture of "Kraft Singles American Pasteurized Process Cheese Food." Our investigators collected labeling for this finished product, which declares milk protein concentrate in its ingredients listing.

  Product labels for Kraft Velveeta Pasteurized Process Cheese Spread, which declare milk protein concentrate in the ingredient list, were also collected by our investigator for review during the subject inspection.

The use of milk protein concentrate in these products constitutes a violation of Section 403(g)(1) of the Act because the products are represented as foods for which standards of identity have been prescribed by regulation and the use of milk protein concentrate in these products does not conform to the standards.

The above is not intended to be an all-inclusive list of deficiencies at your facility. As a food manufacturer, it is your responsibility to assure that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure of these misbranded products and/or injunction of your facility to prevent continued violation of the Act.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to correct these violations, including an explanation of steps that will be taken to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be sent to Patrick J. Brown, Compliance Officer, at the address listed in the letterhead.

Sincerely,

V. R. Connelly

Virginia R. Connelly
Acting District Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

(4)

John Bunting
[illegible]

AUG 13 2003

F03-8050

Dear Mr. Bunting:

In response to your request of June 9, 2003 for copies of all scientific studies on human safety and consumption of Ultra Filtered Milk/Milk Protein Concentrate.
Information regarding ultra filtered milk/milk protein concentrate may be obtained from FDA/Dockets Management Branch/5630 Fishers Lane /Rockville, MD 20857 under the following Dockets: 99P-5198 and 00P-0586.

___Enclosed are the records you requested.

XX We have searched our files and find no responsive information for scientific studies on human safety and consumption of ultra filtered milk/milk protein concentrate.

___Your request is also being referred to one of our component offices.

___In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address: Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal.

Charges will be included in a monthly invoice if your request(s) total more than $15.00. If your monthly total is LESS than $15.00, the material is free. Please DO NOT send payment until you receive an invoice for the total monthly fee.

Reproduction 0 Search $54.00 Review 0 Other 0 Total: $54.00

THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.

Sincerely yours,

FOI OFFICER
Executive Operations Staff
Center for Food Safety
and Applied Nutrition

NO Enclosure

(5) and (9)

June 15, 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
HS 10-DIGIT IMPORTS

AREA/COUNTRIES OF ORIGIN AND COMMODITIES IMPORTED GENERAL IMPORTS		JANUARY - DECEMBER QUANTITIES					JANUARY - APRIL COMPARISONS		
		2000	2001	2002	2003	2004	2004	2005	%CHNG
ARGENTINA	MK PC,WHT/NS,NES 0404901000 MT	54.2	17.6	0.0	0.0	20.0	0.0	40.8	–
AUSTRALIA(*)	MK PC,WHT/NS,NES 0404901000 MT	6,935.5	2,154.1	2,564.4	3.5	75.6	0.0	48.4	–
AUSTRIA	MK PC,WHT/NS,NES 0404901000 MT	0.0	0.0	1.4	0.0	0.0	0.0	0.0	–
BELGIUM-LUXEMBOURG(*)	MK PC,WHT/NS,NES 0404901000 MT	179.8	0.0	0.0	0.0	0.0	0.0	0.0	–
CANADA	MK PC,WHT/NS,NES 0404901000 MT	2,233.7	0.0	168.9	125.1	58.2	15.8	5.5	-65.19
DENMARK(*)	MK PC,WHT/NS,NES 0404901000 MT	960.8	253.7	700.5	620.3	765.7	279.2	238.3	-14.65
DOMINICAN REPUBLIC	MK PC,WHT/NS,NES 0404901000 MT	0.0	0.0	9.5	0.0	0.0	0.0	0.0	–
IRELAND	MK PC,WHT/NS,NES 0404901000 MT	6,916.9	1,649.8	1,902.9	1,567.5	2,762.7	560.5	715.8	27.71
ESTONIA(*)	MK PC,WHT/NS,NES 0404901000 MT	80.0	201.4	237.4	756.0	115.5	16.0	0.0	–
FRANCE(*)	MK PC,WHT/NS,NES 0404901000 MT	931.0	79.8	200.0	0.0	286.2	0.0	0.0	–
GERMANY(*)	MK PC,WHT/NS,NES 0404901000 MT	7,017.8	730.3	4,326.9	2,268.7	19.5	19.5	0.0	–
HUNGARY	MK PC,WHT/NS,NES 0404901000 MT	1,267.3	1,280.2	729.7	135.0	58.9	7.6	17.0	123.68
INDIA	MK PC,WHT/NS,NES 0404901000 MT	0.0	34.0	255.0	0.0	714.0	0.0	408.0	–
ISRAEL(*)	MK PC,WHT/NS,NES 0404901000 MT	0.0	0.0	0.0	13.5	0.0	0.0	0.0	–
JAPAN	MK PC,WHT/NS,NES 0404901000 MT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	–
LITHUANIA(*)	MK PC,WHT/NS,NES 0404901000 MT	167.8	20.0	0.0	0.0	0.0	0.0	0.0	–
MEXICO	MK PC,WHT/NS,NES 0404901000 MT	0.0	1.1	0.0	0.0	0.0	0.0	0.0	–
NETHERLANDS	MK PC,WHT/NS,NES 0404901000 MT	5,443.0	0.0	1,258.6	689.1	40.0	0.0	0.0	–
NEW ZEALAND(*)	MK PC,WHT/NS,NES 0404901000 MT	19,351.6	21,192.4	20,609.5	28,359.6	29,443.6	10,121.3	15,497.5	53.12
POLAND	MK PC,WHT/NS,NES 0404901000 MT	59.1	624.1	659.6	926.6	0.0	0.0	0.0	–
SINGAPORE	MK PC,WHT/NS,NES 0404901000 MT	0.0	0.0	0.0	11.0	0.0	0.0	0.0	–
SWITZERLAND(*)	MK PC,WHT/NS,NES 0404901000 MT	1,228.5	223.6	0.0	3.4	0.0	0.0	0.0	–
UNITED KINGDOM	MK PC,WHT/NS,NES 0404901000 MT	100.6	6.5	1.2	17.4	0.0	0.0	0.0	–
TOTAL	MT	52,927.6	28,468.6	33,625.5	35,496.7	34,360.0	11,019.8	16,971.3	54.01

Data Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics
Note: All zeroes for a data item may show that statistics exist in the other import type. Consumption or General.
(*) denotes a country that is a summarization of its component countries.

**** WARNING ****

Users should use cautious interpretation on QUANTITY reports using mixed units of measure. Commodity groups on a value report will reflect a total of all statistics for each commodity in the group in DOLLARS, whereas a QUANTITY line item will show statistics on the greatest number of like units of measure for grouped commodities.

(6) and (9)

June 16, 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
HS 10-DIGIT IMPORTS

AREA/COUNTRIES OF ORIGIN AND COMMODITIES IMPORTED CONSUMPTION IMPORTS		JANUARY - DECEMBER QUANTITIES					JANUARY - APRIL COMPARISONS		
		2000	2001	2002	2003	2004	2004	2005	%CHNG
ARGENTINA	MLK PROT CNCNTRT 3501101000 MT	10.2	0.0	0.0	0.0	0.0	0.0	0.0	–
AUSTRALIA(*)	MLK PROT CNCNTRT 3501101000 MT	20.0	116.9	1,452.5	5,534.1	4,970.4	1,902.6	1,651.3	-13.21
BELARUS	MLK PROT CNCNTRT 3501101000 MT	20.0	0.0	100.3	80.0	40.0	40.0	0.0	–
CANADA	MLK PROT CNCNTRT 3501101000 MT	0.0	0.0	15.3	0.0	20.0	0.0	20.0	–
CHINA, PEOPLES REPUB	MLK PROT CNCNTRT 3501101000 MT	0.0	5.0	6.0	16.0	18.0	18.0	38.0	111.11
DENMARK(*)	MLK PROT CNCNTRT 3501101000 MT	592.1	280.1	176.2	43.2	42.7	10.8	0.0	–
IRELAND	MLK PROT CNCNTRT 3501101000 MT	2,605.2	460.2	1,299.1	1,395.3	62.5	40.9	489.9	1097.80
ESTONIA(*)	MLK PROT CNCNTRT 3501101000 MT	500.0	200.0	0.0	434.0	6.5	0.0	0.0	–
FRANCE(*)	MLK PROT CNCNTRT 3501101000 MT	917.1	32.8	373.9	907.4	810.5	210.7	224.2	6.41
GERMANY(*)	MLK PROT CNCNTRT 3501101000 MT	632.4	27.5	0.7	149.8	18.5	0.0	25.3	–
HUNGARY	MLK PROT CNCNTRT 3501101000 MT	406.9	279.5	199.4	502.9	173.9	88.4	0.0	–
INDIA	MLK PROT CNCNTRT 3501101000 MT	24.0	101.1	20.0	75.0	30.4	30.4	0.0	–
JAPAN	MLK PROT CNCNTRT 3501101000 MT	13.3	0.0	0.0	0.0	0.0	0.0	0.0	–
LATVIA(*)	MLK PROT CNCNTRT 3501101000 MT	0.0	0.0	0.0	60.8	60.0	60.0	0.0	–
LITHUANIA(*)	MLK PROT CNCNTRT 3501101000 MT	17.0	0.0	0.0	0.0	0.0	0.0	0.0	–
NETHERLANDS	MLK PROT CNCNTRT 3501101000 MT	47.0	24.0	359.9	4.0	76.0	76.0	0.0	–
NORWAY(*)	MLK PROT CNCNTRT 3501101000 MT	0.0	0.0	0.0	19.5	0.0	0.0	0.0	–
NEW ZEALAND(*)	MLK PROT CNCNTRT 3501101000 MT	3,262.5	4,081.2	2,680.8	2,908.3	2,653.3	1,189.6	1,729.2	45.36
POLAND	MLK PROT CNCNTRT 3501101000 MT	230.6	167.0	100.0	201.4	59.5	0.0	39.0	–
RUSSIAN FEDERATION	MLK PROT CNCNTRT 3501101000 MT	88.0	24.0	0.0	0.0	0.0	0.0	0.0	–
SPAIN	MLK PROT CNCNTRT 3501101000 MT	100.0	0.0	0.0	0.0	0.0	0.0	0.0	–
SWITZERLAND(*)	MLK PROT CNCNTRT 3501101000 MT	44.5	0.0	5.4	0.0	193.5	1.6	171.0	10587.50
UNITED KINGDOM	MLK PROT CNCNTRT 3501101000 MT	2,376.6	1,135.0	1,025.5	421.5	0.0	0.0	0.0	–
UKRAINE	MLK PROT CNCNTRT 3501101000 MT	14.0	0.0	0.0	20.2	534.0	142.0	0.0	–
TOTAL	MT	11,921.4	6,934.4	7,815.1	12,773.4	9,769.6	3,810.8	4,387.9	15.14

Data Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics
Note: All zeroes for a data item may show that statistics exist in the other import type. Consumption or General.
(*) denotes a country that is a summarization of its component countries.

**** WARNING ****

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U.S. Department of Health and Human Services
U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition

Grade "A" Pasteurized Milk Ordinance

2001 Revision

May 15, 2002

Grade "A" Pasteurized Milk Ordinance (PMO)
2001 Revision
Section 1 - Section 7

(Return to table of contents.)

An ordinance defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and milk products; requiring permits for the sale of milk and milk products; regulating the inspection of dairy farms and milk plants, the examination, labeling, pasteurization, aseptic processing and packaging and distribution and sale of milk and milk products; providing for the construction of future dairy farms and milk plants; and the enforcement of this *Ordinance* and the fixing of penalties.

Be it ordained by the ... of ...[1] as follows:

SECTION 1. DEFINITIONS

Terms used in this document, not specifically defined herein, are those within Title 21, *Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug, and Cosmetic Act* (FFD&CA) as amended.

The following additional definitions shall apply in the interpretation and the enforcement of this *Ordinance*:

A. **BULK MILK HAULER/SAMPLER:** A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State to sample such products.

B. **BULK MILK PICKUP TANKER:** A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.

C. **BUTTERMILK:** Buttermilk is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8 1/4 percent of milk solids not fat.

D. **CONCENTRATED MILK:** Concentrated milk is a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which when combined with potable water in accordance with instructions printed on the container label, results in a product conforming with the milkfat and milk solids not fat levels of milk as defined in this Section.

E. **CONCENTRATED MILK PRODUCTS:** Concentrated milk products shall be taken to mean and to include homogenized concentrated milk, concentrated nonfat milk, concentrated reduced fat or low fat milk, and similar concentrated products made from concentrated milk or concentrated non-fat milk, which when combined with potable water in accordance with instructions printed on the container label, conform with the definitions of the corresponding milk products in this Section.

F. **DAIRY FARM:** A dairy farm is any place or premises where one (1) or more lactating animals (cows, goats or sheep) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station.

G. **DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. This person is an employee of the Regulatory Agency and is evaluated at least once every two (2)-year period by a State Sampling Surveillance Officer.

H. **EGGNOG OR BOILED CUSTARD:** Eggnog or boiled custard is the product defined in 21 CFR 131.170.

I. **FOOD ALLERGENS:** Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

Reference: FDA Compliance Policy Guide 555.250 - Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens available on the Internet at: http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm

J. **FROZEN MILK CONCENTRATE:** Frozen milk concentrate is a frozen milk product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.

K. **GOAT MILK:** Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2 1/2 percent milkfat and not less than 7 1/2 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include goat milk.

L. **GRADE "A" DRY MILK AND WHEY PRODUCTS:** Grade "A" dry milk and whey products

are products which have been produced for use in Grade "A" pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the most current revision of the *Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey - Supplement I to the Grade "A" Pasteurized Milk Ordinance* (DMO).

M. **MILK DISTRIBUTOR:** A milk distributor is any person who offers for sale or sells to another any milk or milk products.

N. **MILK PLANT:** A milk plant is any place, premises; or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, packaged, or prepared for distribution.

O. **MILK PRODUCER:** A milk producer is any person who operates a dairy farm and provides, sells or offers milk for sale to a milk plant, receiving station or transfer station.

P. **MILK PRODUCTS:** Milk products include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated milk, concentrated milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this Section, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.[2,3]

Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term.

This Definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged.

Milk and milk products which have been retort processed after packaging or which have been concentrated, condensed or dried are included in this Definition only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade "A" as described in Section 4.

This Definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.

Q. **MILK TANK TRUCK:** A milk tank truck is the term used to describe both a bulk milk pickup tanker and a milk transport tank.

R. **MILK TANK TRUCK CLEANING FACILITY:** Any place, premises, or establishment, separate from a milk plant, receiving station or transfer station, where a milk tank truck is cleaned

and sanitized.

S. **MILK TANK TRUCK DRIVER:** A milk tank truck driver is any person who transports raw or pasteurized milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

T. **MILK TRANSPORT TANK:** A milk transport tank is a vehicle, including the truck and tank, used by a bulk milk hauler/sampler to transport bulk shipments of milk from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.

U. **MILK TRANSPORTATION COMPANY:** A milk transportation company is the person responsible for a milk tank truck(s).

V. **OFFICIAL LABORATORY:** An official laboratory is a biological, chemical or physical laboratory, which is under the direct supervision of the Regulatory Agency.

W. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

X. **PASTEURIZATION:** The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one (1) of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
63°C (145°F)*	30 minutes
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

*If the fat content of the milk product is ten percent (10%) or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

69°C (155°F)	30 minutes

80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

Provided further, that nothing shall be construed as barring any other pasteurization process, which has been recognized by FDA to be equally efficient and which is approved by the Regulatory Agency.

Y. **PERSON:** The word "person" shall include any individual, plant operator, partnership, corporation, company, firm, trustee, association or institution.

Z. **RECEIVING STATION:** A receiving station is any place, premises, or establishment where raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

AA. **RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS:** Reconstituted or recombined milk and/or milk products shall mean milk or milk products defined in this Section which result from reconstituting or recombining of milk constituents with potable water when appropriate.[4]

BB. **REGULATORY AGENCY:** The Regulatory Agency shall mean the ... of the ...[1] or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency having jurisdiction and control over the matters embraced within this *Ordinance*.

CC. **SHEEP MILK:** Sheep milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include sheep milk.

DD. **TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another.

SECTION 2. ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person shall, within the ... of ...[1], or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

Any adulterated or misbranded milk or milk product may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.

ADMINISTRATIVE PROCEDURES

This Section of the *Ordinance* shall be used in impounding the products of, or preferring charges against, persons who adulterate or misbrand their milk or milk products; or label them with any grade designation not authorized by the Regulatory Agency under the terms of this *Ordinance;* or who sell or deliver ungraded milk or milk products, except as may be permitted under this Section in an emergency. An emergency is defined as a general and acute shortage in the milk shed, not simply one (1) distributor's shortage.

SECTION 3. PERMITS

It shall be unlawful for any person who does not possess a permit from the Regulatory Agency of the ... of ...[1] to bring into, send into or receive into the ... of ...[1] or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk or milk products defined in this *Ordinance*. Provided, that grocery stores, restaurants, soda fountains and similar establishments where milk or milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

Only a person who complies with the requirements of this *Ordinance* shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations.

The Regulatory Agency shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this *Ordinance*; or whenever the permit holder has interfered with the Regulatory Agency in the performance of its duties. Provided, that the Regulatory Agency shall, in all cases except where the milk or milk product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit, notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such vio- lation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the Regulatory Agency before making any order of suspension effective. A suspension of permit shall remain in effect until the violation(s) has been corrected to the satisfaction of the Regulatory Agency.

Upon notification, acceptable to the Regulatory Agency, by any person whose permit has been suspended, or upon application within forty-eight (48) hours of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the Regulatory Agency shall within seventy-two (72) hours proceed to a hearing to ascertain the facts of such violation(s) or interference and upon evidence presented at such hearing shall affirm, modify or rescind the suspension or intention to suspend.

Upon repeated violation(s), the Regulatory Agency may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing. This Section is not intended to preclude the institution of court action as provided in Sections 5 and 6.

ADMINISTRATIVE PROCEDURES

ISSUANCE OF PERMITS: Every milk producer, milk distributor, bulk milk hauler/sampler, milk tank truck[5], milk transportation company and each milk plant, receiving station, milk tank truck cleaning facility and transfer station operator shall hold a valid permit. The permit for a milk tank truck(s) may be issued to the milk transportation company. Milk producers who transport milk or milk products, only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler's permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

SUSPENSION OF PERMIT: When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.

The Regulatory Agency may forego suspension of the permit, provided the product or products in violation are not sold or offered for sale as Grade "A" product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided product or products in violation are not sold or offered for sale as Grade "A" product.

HEARINGS: If a State Administrative Procedures Act, which provides procedures for administrative hearings and judicial review of administrative determinations, is available, the Act shall be made applicable by reference to the hearings provided for in the *Ordinance*. If such Administrative Procedures Act is not available, appropriate procedures, including provision for notice, hearing officer, their authority, record of hearing, rules of evidence and court review shall be established by appropriate authority.

REINSTATEMENT OF PERMITS: Any producer, distributor, bulk milk hauler/sampler, milk transportation company or plant operator whose permit has been suspended may make written application for the reinstatement of their permit.

When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling temperature standards, the Regulatory Agency, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the Regulatory Agency may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period and the Regulatory Agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such notification, the Regulatory Agency shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

When a permit suspension has been due to positive drug residues, the permit shall be reinstated in accordance with the provisions of Appendix N.

SECTION 4. LABELING

All bottles, containers and packages containing milk or milk products defined in Section 1 of this *Ordinance* shall be labeled in accordance with the applicable requirements of the FFD&CA, the *Nutrition Labeling and Education Act* (NLEA) of 1990, and regulations developed thereunder, the CFR, and in addition, shall comply with applicable requirements of this Section as follows:

All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the plant where pasteurized, ultra-pasteurized or aseptically processed.

2. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.

3. The word "Goat" or "Sheep" shall precede the name of the milk or milk product when the product is or is made from goat or sheep milk respectively.

4. The words "Grade "A" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

5. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

1. Shipper's name, address and permit number. Each milk tank truck containing milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS listed Plant Number, for farm groups listed with a plant, on the weight ticket or manifest.

2. Permit identification of hauler, if not an employee of the shipper.

3. Point of origin of shipment.

4. Tanker identification number.

5. Name of product.

6. Weight of product.

7. Temperature of product when loaded.

8. Date of shipment.

9. Name of supervising Regulatory Agency at the point of origin of shipment.

10. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated.

11. Seal number on inlet, outlet, wash connections and vents.

12. Grade of product.

All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.

Each milk tank truck containing milk shall be accompanied by documentation, weigh ticket or manifest, which shall include the IMS BTU Identification Number(s) or the IMS Listed Plant Number, for farm groups listed with a plant.

ADMINISTRATIVE PROCEDURES

LABELING OF EMERGENCY SUPPLIES: When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section 2, the label must bear the designation "ungraded". When such labeling is not available, the Regulatory Agency shall take immediate steps to inform the public that the particular supply is ungraded and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

IDENTITY LABELING: "Identity", as used in this Section, is defined as the name and address of the milk plant at which the pasteurization, ultra-pasteurization or aseptic processing takes place. It is recommended that the voluntary national uniform coding system for the identification of pasteurization plants, at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles or containers. Provided, that the location of the plant at which the contents were pasteurized, ultra-pasteurized, or aseptically processed is also shown, either directly or by a code. This requirement is necessary in order to enable the Regulatory Agency to identify the source of the pasteurized, ultra-pasteurized, or aseptically processed milk. The street address of the plant need not be shown when only one plant of a given name is located within the municipality.

The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

MISLEADING LABELS: The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label, when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. The use of super grade designations shall not be permitted. Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized, or aseptically processed milk when properly enforced, will ensure that

this grade of milk will be as safe as milk can practically be made. Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or misleading.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, milk tank truck cleaning facility and transfer station whose milk or milk products are intended for consumption within ...of...[1] or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months;

2. Inspect each such bulk milk hauler/sampler's pickup and sampling procedures at least once every twenty-four (24) months;

3. Inspect each milk plant and receiving station at least once every three (3) months;

4. Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months; and

5. Inspect each dairy farm at least once every six (6) months.[6]

Should the violation of any requirement set forth in Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B, be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection shall be used to determine compliance with the requirements of Section 7 or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B. Any violation of the same requirement of Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B on such second inspection, shall call for permit suspension in accordance with Section 3 and/or court action. Provided, that when the Regulatory Agency finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or

2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or

3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit as provided for in Section 3 of this *Ordinance.* Provided, that in the case of dairy plants producing aseptically processed milk and milk products, when an inspection of the dairy plant and its records reveal that the process used has been less than the required scheduled process,

it shall be considered an imminent hazard to public health and the Regulatory Agency shall take immediate action to suspend the permit of the plant for the sale of aseptically processed milk and milk products in conformance with Section 3 of this *Ordinance*.

One (1) copy of the inspection report shall be handed to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the Regulatory Agency upon request. An identical copy of the inspection report shall be filed with the records of the Regulatory Agency.

Every milk producer, bulk milk hauler/sampler, milk transportation company or milk tank truck driver, distributor or plant operator shall, upon request of the Regulatory Agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of this *Ordinance*. A distributor or plant operator shall furnish the Regulatory Agency, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records.

It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance* which is entitled to protection as a trade secret, including information as to the quantity, quality, source or disposition of milk or milk products, or results of inspections or tests thereof, to use such information to their own advantage or to reveal it to any unauthorized person.

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms and transfer stations the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for milk plants and receiving stations the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

One (1) milk tank truck inspection every twelve (12) months, or bulk milk hauler/sampler pickup and sampling procedures inspection each twenty-four (24) months, or one (1) producer inspection every six (6) months or one (1) plant inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/ samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit and/or court action, if two (2) successive inspections disclose a violation of the same requirement.

Experience has demonstrated that strict enforcement of the *Ordinance* leads to a better and friendlier relationship between the Regulatory Agency and the milk industry than does a policy of enforcement,

which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor the requirement that has been violated, discuss a method for correction and set a time for correcting the violated requirement.

The penalties of suspension or revocation of permit, and/or court action, are provided to prevent continued violation of the provisions of this *Ordinance*, but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the Regulatory Agency is authorized, in Section 3, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor upon the first violation of any of the sanitation requirements listed in Section 7. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor found violating any requirement must be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three (3) days. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator or by the posting of an inspection report, as required by this Section. After receipt of a notice of violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall have an opportunity to appeal the sanitarian's interpretation to the Regulatory Agency or request an extension of the time allowed for correction.

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING MILK PLANTS: Because aseptically processed milk and milk products are stored at room temperature and are not refrigerated after processing they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by the Regulatory Agency to suspend the permit must be initiated in order to protect the public health. The Regulatory Agency shall stop the sale of all under-processed product and follow at least the minimum requirements of 21 CFR 113.89 before releasing any product. (See Appendix L.)

CERTIFIED INDUSTRY INSPECTION: The Regulatory Agency may certify industry personnel, with their consent, to carry out cooperatively the provisions of this *Ordinance* with respect to the supervision of dairy farms, bulk milk haul/sampler's pickup and sampling procedures, and/or milk tank trucks. States utilizing certified industry inspections shall have on file and available for review, a written program that describes how the requirements of this *Ordinance* and related documents shall be implemented. Delegation of the inspection and evaluation of bulk milk hauler/sampler's pickup and sampling procedures shall be done by the Sampling Surveillance Officer in accordance with the *Evaluation of Milk Laboratories* (EML).

Reports of all inspections conducted by such personnel to determine compliance with the provisions of this *Ordinance* shall be maintained by the industry at a location acceptable to the Regulatory Agency. The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of permits. Initial inspections and change of market inspections are required and shall be conducted by the Regulatory Agency in conjunction with the Certified Industry Inspector.

When a producer changes market, the producer records for the preceding twenty-four (24) months shall

be transferred with the producer, through the Regulatory Agency, and will continue to be a part of the producer's record.

Industry personnel shall be certified every three (3) years by the Regulatory Agency.

At least annually, the Certified Industry Inspector shall attend an educational seminar provided by the Regulatory Agency, or equivalent training acceptable to the Regulatory Agency.

At least once in each six (6) month period, the Regulatory Agency shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of the Regulatory Agency's written plan and requirements of this *Ordinance* and related documents.

Initial certification by the Regulatory Agency shall not be made during the course of an official inspection. Re-certification by the Regulatory Agency may be conducted during the course of an official inspection.

Purpose of Certification: The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of this *Ordinance,* related documents, and the Regulatory Agency's procedures.

Designation of Individuals to Be Certified: Candidates shall submit requests for certification to the Regulatory Agency. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis.

Recording of Qualification Data: Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by the Regulatory Agency as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination.

Field Procedure: Only one (1) applicant shall be certified at a time. The certification is to be conducted without prompting from the Regulatory Agency or comparison of inspection results in any way until the entire procedure is completed. Initial certification shall not be made during the course of an official inspection by the Regulatory Agency.

At least twenty-five (25) randomly selected dairy farms and/or five (5) milk tank trucks shall be visited. After the necessary inspections have been completed, the Regulatory Agency shall compare their results with those of the candidate. The percentage agreement for each Item of sanitation shall be determined by dividing the number of agreements by the total number of dairy farms and/or milk tank trucks inspected.

Criteria for Certification: In order to be certified, an industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant.

Duration of Certification: Certification of industry inspection personnel shall be for a period not

exceeding three (3) years from the date of formal certification or re-certification unless revoked.

Re-certification: The Regulatory Agency shall notify the certified industry inspector of the need for certification renewal at least sixty (60) days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three (3) year period, by following the procedures outlined above. Provided, that re-certification may be conducted during the course of an official inspection by the Regulatory Agency.

Reports and Records: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume of the percentage agreement on individual items, shall be retained by the Regulatory Agency.

Revocation of Certification: The certification of an industry inspector may be revoked by the Regulatory Agency upon a finding that the inspector is:

1. Not in agreement with the Regulatory Agency at least eighty percent (80%) of the time on Items of sanitation in a field examination conducted as described in the **Field Procedure** outlined above; or

2. Not complying with the established administrative procedures of the Regulatory Agency for the program; or

3. Failing to carry out the provisions of this *Ordinance* in the course of the inspector's work.

INSPECTION REPORTS: A copy of the inspection report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection forms are included in Appendix M.

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from plants offering such products for sale, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or lowfat milk, flavored nonfat (skim) milk, each fat level of reduced fat or lowfat milk and each milk product defined in this *Ordinance*, (including aseptically processed milk and milk products for drug residue tests) shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant.

Samples of milk and milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk or milk products are obtained.

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

Required bacterial counts, drug tests, coliform determinations, phosphatase and cooling temperature checks shall be performed on pasteurized milk and milk products. Required drug residue tests shall be performed on aseptically processed milk and milk products.

Whenever two (2) of the last four (4) consecutive bacterial counts, except those for aseptically processed milk and milk products, somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect so long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts (except those for aseptically processed milk and milk products), somatic cell counts, coliform determinations or cooling temperatures.

Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale.

Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

Whenever a drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.

Whenever a container or containers of aseptically processed milk or milk product is found to be unsterile, due to under-processing, the Regulatory Agency shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products from the lot that were found to contain one (1) or more unsterile units shall be recalled and disposed of as directed by the Regulatory Agency.

Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the EML. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM). Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. Assays of milk and milk products to which vitamin(s) A and/or D have been added, shall be made at least annually in a laboratory which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the EML manual.

In addition, all facilities fortifying products with vitamins must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamin A and D used with the amount of products produced and indicate a percent of expected use, plus or minus.

ADMINISTRATIVE PROCEDURES

ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (See Appendix E - Examples of Three (3)-out-of-Five (5) Compliance Enforcement Procedures).

Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this *Ordinance*. Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by the Regulatory Agency. Dairy plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. The Regulatory Agency may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of the bacterial standards has existed.

LABORATORY TECHNIQUES: Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA 2400 series forms, SMEDPand OMA. The procedures shall be those specified therein for:

1. Standard plate count at 32°C (agar or Petrifilm method).

2. Alternate methods, including the Plate Loop Count and the BactoScan FC for viable counts for raw milk, and the Petrifilm method for pasteurized milk and milk products at 32°C.

3. Coliform test with solid media or Petrifilm method at 32°C for all milk and milk products, and the Petrifilm High Sensitivity Coliform Count method for all milk and milk products, except unflavored whole, reduced or low fat and nonfat (skim) milk.

4. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk, or pasteurized milk, or that particular type of pasteurized milk product at current safe or tolerance levels shall be used for each drug of concern.

Regulatory action shall be taken on all confirmed positive results. (See Appendix N.) A result shall be considered positive if it has been obtained by using a method, which has been evaluated and deemed acceptable by FDA and accepted by the NCIMS at levels established in memoranda transmitted periodically by FDA as required by Section III of Appendix N.

5. Screening and Confirmatory Methods for the Detection of Abnormal Milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.

When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time.

5a. Milk (Non-Goat): Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting.

5b. Goat Milk: In addition to the above mentioned tests, the Wisconsin Mastitis Test or California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one (1), respectively.

Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Pyronine Y-Methyl green stain or "New York modification" shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.

6. APHA, AOAC, or Electronic Phosphatase Tests: The phosphatase test is an index of the efficiency of the pasteurization process. In the event the laboratory phosphatase test is positive, the cause shall be determined immediately. Where the cause is improper pasteurization, it shall be corrected. When a laboratory phosphatase test is positive, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section 7, Item 16p, the Regulatory Agency should immediately conduct field phosphatase test at the plant. (See Appendix G.)

7. Vitamin testing shall be performed using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods.

8. Any other tests, which have been approved by FDA to be equally accurate, precise and practical.

9. All standards used in the development and use of drug residue detection methods designed for Grade "A" PMO monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method must define the standard to be used.

10. Procedural or reagent changes for official tests must be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories.

SAMPLING PROCEDURES: SMEDP contains guidance for sampling of products. (See Appendix G. for a reference to drug residues in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. See Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)

SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS

All Grade "A" raw milk for pasteurization, ultra-pasteurization, or aseptic processing and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall be produced, processed and pasteurized, ultra-pasteurized, or aseptically processed to conform to the following chemical, bacteriological and temperature standards and the sanitation requirements of this Section.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Table 1. Chemical, Bacteriological and Temperature Standards		
GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).
	Bacterial Limits.....	Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization.
	Drugs.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques.
	Somatic Cell Count*.....	Individual producer milk not to exceed 750,000 per mL.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial Limits**.....	20,000 per mL, or gm.***
	Coliform****.....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	Phosphatase****.....	Less than 350 milliunits/L for fluid products and less than 500 for other milk products by the Fluorometer or Charm ALP or equivalent.
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.
GRADE "A" ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113.3(e)(1)*****
	Drugs**.....	No positive results on drug residue detection methods as referenced in

		Section 6 - Laboratory Techniques that have been found to be acceptable for use with aseptically processed milk and milk products.

* Goat Milk 1,000,000 per mL

** Not applicable to cultured products

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (See the current edition of the SMEDP)

**** Not applicable to bulk shipped heat-treated milk products

***** 21 CFR 113.3(e)(1) contains the definition of "COMMERCIAL STERILITY"

Footnotes

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United States General Accounting Office

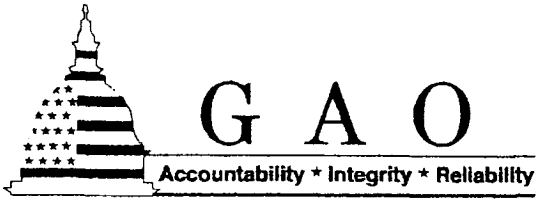
GAO

Report to Congressional Requesters

March 2001

DAIRY PRODUCTS

Imports, Domestic Production, and Regulation of Ultra-filtered Milk



GAO-01-326

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Abbreviations

AMS Agricultural Marketing Service
FDA Food and Drug Administration
MPC milk protein concentrates
USDA U.S. Department of Agriculture

GAO
Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

March 5, 2001

Congressional Requesters

Milk is primarily composed of protein, fat, lactose, water, minerals, and vitamins. The ultra-filtration process for milk, developed in the 1970s, removes most of the fluid components, leaving a high concentration of milk protein that allows cheese and other manufacturers to produce their products more efficiently. Ultra-filtered milk is also a common ingredient in high-protein sports drinks, energy bars, and nutrition supplements. It comes in two forms: (1) a dry powder, which is currently all imported and (2) a thick liquid, referred to as "wet," which is produced domestically. Dry ultra-filtered milk imports enter the United States under the U.S. Customs Service's broader classification of milk protein concentrates, which includes similar products made by other processes, such as blending nonfat dry milk with highly concentrated milk proteins. U.S. milk producers have expressed concern that imported ultra-filtered milk may displace domestically produced milk used to make cheese.

For regulatory purposes, cheese products fall into two broad categories—standardized and nonstandardized cheese. The Food and Drug Administration (FDA) regulates certain cheeses—such as cheddar or mozzarella—through its "standards of identity" regulations to ensure that they meet specifications for ingredients and characteristics. (See app. I for a list of standardized cheeses and related cheese products.) FDA officials stated that ultra filtration of milk is an acceptable in-plant procedure during the manufacture of cheese. However, the use of ultra-filtered milk as a starting ingredient to make cheese is not allowed by FDA's "standards of identity" regulations. In 1996, FDA allowed an exception to its standard for a pilot project producing ultra-filtered milk on a farm in New Mexico for shipment to one cheese plant in Minnesota. FDA does not specify the ingredients and characteristics of nonstandardized cheese products, such as pizza cheese. Producers of nonstandardized cheese products may use wet or dry ultra-filtered milk as ingredients.

To address U.S. dairy producers' concerns about the use of ultra-filtered milk, you requested that we provide information on (1) trends in ultra-filtered milk imports, including federal trade restrictions on these imports; (2) the use of domestically produced ultra-filtered milk in U.S. cheese making; and (3) FDA's and the states' efforts to enforce FDA's standards of identity regulations, particularly the use of ultra-filtered milk in cheese production. To obtain this information, we interviewed officials and

obtained data from FDA; the U.S. Department of Agriculture (USDA); the U.S. Customs Service; industry trade associations; domestic and foreign dairy companies; and agricultural academicians. We also obtained information from state officials in Vermont and Wisconsin about their efforts to inspect cheese-making plants and the extent to which they coordinate their efforts with FDA.

Results in Brief

No specific data on the amount of ultra-filtered milk imports exists because these imports fall under the broader U.S. Customs Service's classification of milk protein concentrates. However, milk protein concentrate imports grew rapidly from 1990 to 1999—from 805 to 44,878 metric tons—and nearly doubled between 1998 and 1999. Six countries—New Zealand, Ireland, Germany, Australia, the Netherlands, and Canada—accounted for 95 percent of the imports in 1999. Exporters of milk protein concentrates face few U.S. import restrictions: no quotas limiting the import quantity, low duties, and a broadly defined classification under which these products are imported that includes concentrates of any type if they contain 40- to 90-percent milk protein. FDA believes the milk protein concentrates pose minimal safety risks.

Similarly, there is little data on the amount and use of domestically produced wet ultra-filtered milk in U.S. cheese-making plants. According to USDA and state sources, a total of 22 dairy plants nationwide and 4 large dairy farms in New Mexico and Texas produce wet ultra-filtered milk. The plants primarily produce and use the ultra-filtered milk in the process of making cheese. The four farms transport their product primarily to cheese-making plants in the Midwest, where most is used to make standardized cheeses.

FDA relies on its own inspections, and those it contracts with 37 states, to enforce its standards of identity regulations. In addition to these federally funded inspections, some states conduct their own inspections of cheese plants for compliance with standards of identity requirements under state law. In fiscal year 1999, FDA and state contract inspectors reported no violations surrounding the use of imported ultra-filtered milk or milk protein concentrates in making standardized cheese. FDA inspected nine cheese plants in fiscal year 1999 for compliance with food labeling and economic regulations, which generally would include the standards of identity for cheese. None of these inspections were done exclusively to check for compliance with standards of identity for cheese. Similarly, states conducting inspections on FDA's behalf in fiscal year 1999 did not exclusively monitor compliance with standards for cheese. In 2000,

Vermont state inspectors found that two cheese plants were using imported milk protein concentrates to make standardized cheeses in violation of federal and state regulations. The state issued warning letters, and the plants discontinued this practice.

We provided a draft of this report to FDA for its review and comment. FDA generally agreed with the draft and provided some specific comments, which we have incorporated where appropriate.

Background

Ultra-filtration technology separates the components of milk according to their size by passing milk under pressure through a thin porous membrane. Specifically, ultra filtration allows the smaller lactose, water, mineral, and vitamin molecules to pass through the membrane, while the larger protein and fat molecules—key components for making cheese—are retained and concentrated.[1] (See app. II for further explanation of ultra filtration and its use in the cheese-making process.) Although ultra-filtration equipment is expensive, it creates an ingredient well suited for making cheese and other food products requiring a high milk protein content. In addition, the removal of water and lactose reduces the volume of milk, and thereby lowers its transportation and storage costs. All ultra-filtered milk imported into the United States in 2000 was in a dry powder form.

The U.S. Customs Service's milk protein concentrates classification includes processed milk products containing between 40 percent and 90 percent protein. Imported powdered milk products with less than 40 percent protein are usually classified as nonfat dry milk and are subject to a tariff-rate quota that limits the amount that can be imported at a low tariff rate. In addition to ultra-filtered milk products, the milk protein concentrate classification includes concentrates made through other processes, such as blending nonfat dry milk with highly concentrated proteins. These products are often tailored to a specific use in products requiring a protein ingredient.

FDA's standards of identity regulations permit cheese manufacturers under the "alternate make" provisions to use ultra filtration as an acceptable procedure during the cheese-making process. Consequently, milk that has been ultra-filtered as an integral part of the cheese-making

[1]Depending on the intended use of the ultra-filtered milk product, the fat in whole milk may be removed before filtration.

process is acceptable as a component of a standardized cheese, according to FDA. In 1999 and 2000, organizations representing cheese makers petitioned FDA to amend its cheese standards to expand its definition of milk to include wet ultra-filtered milk. The industry petitioners requested permission to use wet ultra-filtered milk from external sources as an ingredient in standardized cheeses because it would increase the efficiency of cheese manufacturing and would explicitly recognize filtered milk products as interchangeable with other forms of milk. One of the industry petitioners, who had also asked FDA to allow the use of the dry ultra-filtered milk in standardized cheeses, later withdrew this part of the request when U.S. milk producers raised concerns that increased imports might displace domestic milk products. FDA has not yet acted on the petitions.

U.S. Imports of Milk Protein Concentrates, Including Dry Ultra-filtered Milk, From 1990 Through 1999

Specific data on U.S. imports of ultra-filtered milk do not exist because these imports are included in the broader classification of milk protein concentrates.[2] Milk protein concentrate imports increased 56-fold from 1990 to 1999. In 1999, they came primarily from New Zealand, Ireland, Germany, Australia, the Netherlands, and Canada. Milk protein concentrates are used as ingredients in cheese, frozen desserts, bakery products, and sports and other nutritional supplement products. The United States has no quota restrictions on milk protein concentrate imports, and duties are low. FDA officials told us that these imports pose little food safety risk and therefore receive minimal monitoring.

Milk Protein Concentrate Imports Rose Rapidly During the 1990s

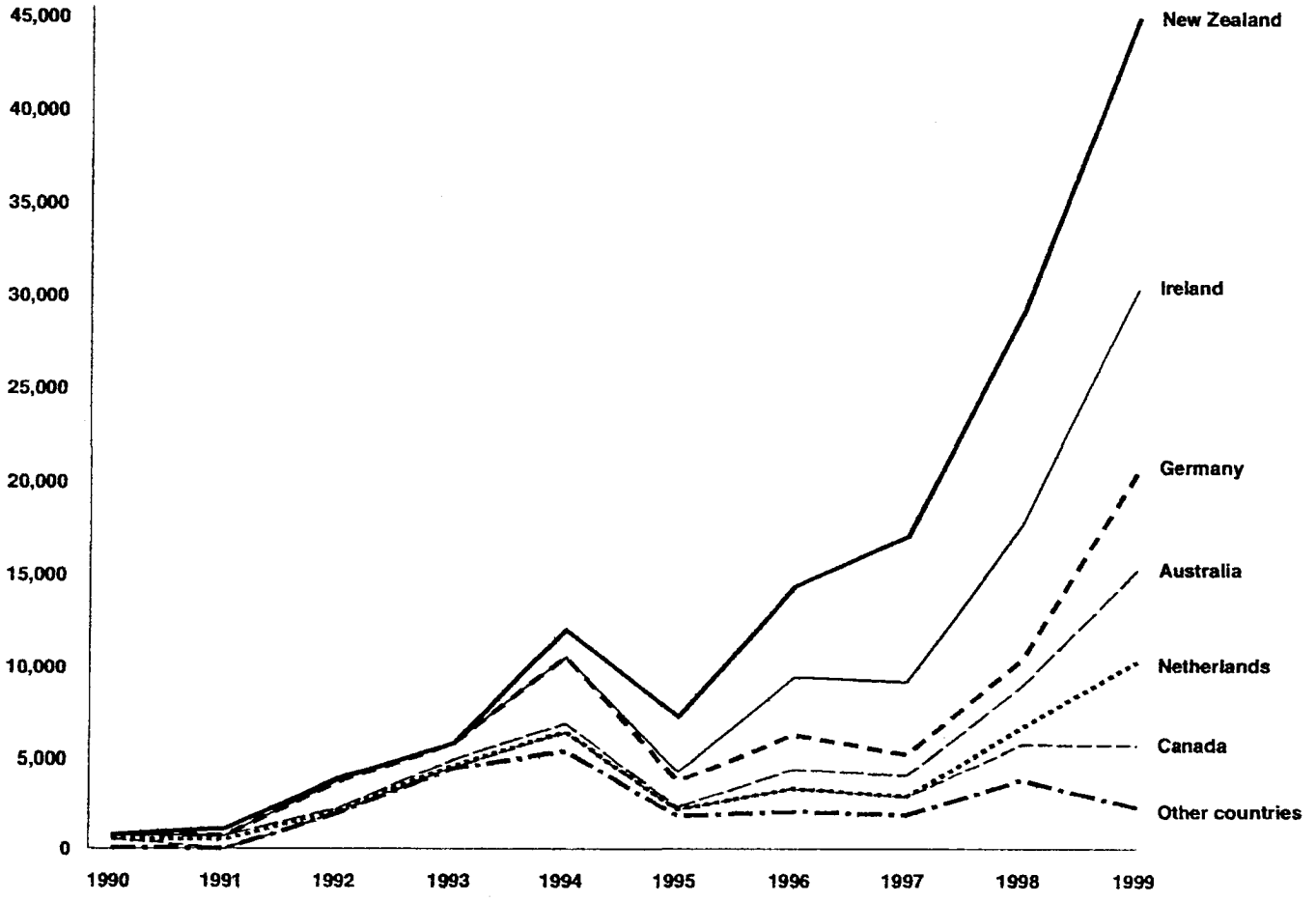
U.S. milk protein concentrate imports grew from 805 metric tons in 1990 to 7,288 metric tons in 1995 to 44,878 metric tons in 1999 (see fig. 1). Imports almost doubled in 1999 alone. The volume of imported milk protein in these concentrates was approximately equivalent to 0.8 percent to 1.8 percent of the total U.S. production of milk protein in 1999.[3] The estimate's range reflects the fact that imported milk protein concentrates may

[2]The classification number 0404.90.10 in the *Harmonized Tariff Schedule of the United States, Annotated* is intended for nonfat varieties of milk protein concentrate, U.S. Customs Service officials said. No imports were reported in classification number 0404.90.30, which is for milk protein concentrates made from whole milk, i.e., including fat.

[3]This estimate is based on USDA's National Agricultural Statistics Service's estimate that U.S. dairy farms produced 162.7 billion pounds of milk in 1999 and assumes that, on average, about 3 percent of milk is true protein and that the protein reported in milk protein concentrates is true protein.

contain between 40-and 90-percent protein. The U.S. Customs Service does not collect data on the protein percentage of milk protein concentrate imports.

Figure 1: Trend in Milk Protein Concentrate Imports to the United States for Six Major Exporting Countries and Others, 1990-1999

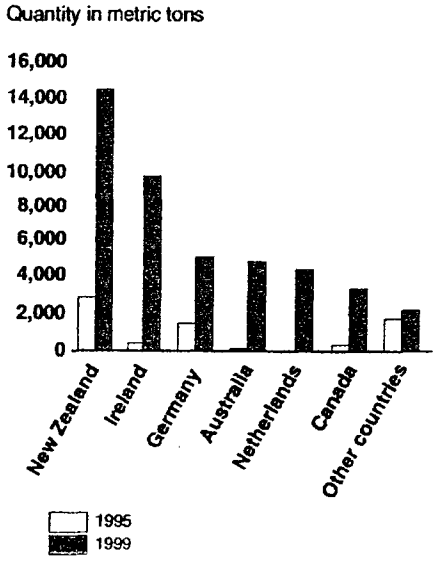


Source: Import quantities as compiled by the U.S. Census Bureau from the U.S. Customs Service data.

The total number of countries exporting milk protein concentrates to the United States grew from 4 to 16 from 1990 to 1999. (See app. III.) Australia was the only country to export milk protein concentrates in each of the 10 years. Figure 2 shows the growth in imports for each major exporter and other countries from 1995 to 1999. The share of imports among the six largest exporting countries rose from 75 to 95 percent during this 5-year period. Although the U.S. Customs Service does not categorize its data on

milk protein concentrate imports according to the manufacturing process used, representatives of Australian and New Zealand exporters assured us that their milk protein concentrate exports were all made using ultra filtration. Conversely, Canadian government officials said all of their country's milk protein concentrate exports to the United States are made by blending milk proteins.

Figure 2: Comparison of Milk Protein Concentrate Imports, 1995 vs. 1999



Source: Import quantities as compiled by the U.S. Census Bureau from U.S. Customs Service data.

U.S. and foreign industry executives told us that U.S. milk protein concentrate imports rose rapidly in recent years primarily because of (1) the relationship between the U.S. and international prices of milk protein, especially nonfat dry milk, and (2) the growth of the U.S. nutritional foods industry and many other new products using milk protein concentrates. According to these executives, international milk prices were below U.S. milk prices in recent years, giving U.S. dairy food manufacturers a financial incentive to substitute imported milk protein concentrates for domestic milk in products such as nonstandardized cheese. This price differential primarily stimulated U.S. imports of milk protein concentrates having lower percentages of protein—between 40 and 56 percent. More recently, U.S. demand for these milk protein concentrates has decreased, according to an Australian exporter, because the international price of milk protein is near the U.S. price.

The strong growth of the U.S. nutritional foods industry has created new demand for high-protein milk protein concentrates that are 70- to 85-percent protein. Representatives of Australia and New Zealand exporters told us that this industry grew out of extensive research and development to create nutritional supplements for athletes, the elderly, and health conscious individuals. Milk protein concentrates provide an important source of protein in these nutritional products. Because high-protein milk protein concentrates are often customized for use in specific end products, their producers and exporters can sell them at higher prices than the equivalent amount of domestic milk protein, the exporters said. Despite their higher prices, the demand for these specialized high-protein products in the United States is strong. Industry executives noted that high-protein milk protein concentrate imports have not displaced domestic milk supplies because they are filling the growing demand for new nutritional products. In addition, a trade association representative and an academic expert noted that economic disincentives have prevented U.S. production of dry milk protein concentrates.

Imported Milk Protein Concentrates Are Used in Many Food Products

Federal agencies and industry trade associations do not collect data on U.S. companies' use of imported milk protein concentrates because this information is considered proprietary. According to milk protein concentrate exporters, U.S. cheese, frozen dessert, bakery, and nutritional foods industries primarily use the dry milk protein concentrate imports. In particular, dry milk protein concentrates containing lower levels of protein—42 to 56 percent—can be added to the raw milk used to make cheese, ensuring a consistent composition regardless of the seasonal variations in milk. Various concentrations of milk protein are also used in ice cream[4] and other frozen desserts, bakery and confection products, and nonstandardized cheese. Milk protein concentrates containing higher protein levels—70 to 85 percent—are chiefly used in sport-, adult-, and hospital-nutrition products. Concentrates containing 90-percent protein are especially useful for manufacturers seeking lactose- and sugar-free claims for their products, according to a major exporter. (See app. IV for more details on the composition and uses of dry milk protein concentrate imports provided by some exporters.)

[4]FDA's standard of identity regulations for ice cream specifically provide for the use of milk protein concentrate as an ingredient (see 21 C.F.R., part 135).

Exporters of Milk Protein Concentrates to the United States Face Few Restrictions

The U.S. Customs Service and FDA share responsibility for monitoring milk protein concentrate imports for compliance with trade or food safety requirements. Unlike nonfat dry milk imports, which have less than a 40 percent protein content, the United States does not use a tariff-rate quota to restrict the quantity of milk protein concentrate imports. The United States imposes a duty of $0.0037 per kilogram[5] on all milk protein concentrate imports except Canadian imports, which are duty-free under the North American Free Trade Agreement. The milk protein concentrates classification, which is intended to include all nonfat dry milk powder containing between 40 and 90 percent protein regardless of its method of production, allows a broad range of milk protein concentrates to enter the United States, according to the U.S. Customs Service.[6]

FDA and USDA's Food Safety and Inspection Service are responsible for ensuring that imported food products are safe, wholesome, and properly labeled.[7] FDA and USDA work with the U.S. Customs Service to ensure the safety of imported food products by monitoring and testing samples of imported foods. Customs uses a computer system containing information provided by the milk protein concentrate importers and FDA-developed screening criteria to determine which shipments may be automatically released and which should be subjected to inspection or laboratory testing.[8] Products such as milk protein concentrates, which are believed to pose minimal safety risks, are frequently released automatically. FDA annually inspects or conducts laboratory analyses on less than 2 percent of all types of imported food shipments. FDA officials told us that they have little concern about the safety of dry milk protein concentrates because the products are treated with heat during pasteurization and drying, which kills pathogens.

In addition to screening milk protein concentrate imports, the United States has agreements with Australia, Belgium, Denmark, France, Ireland, the Netherlands, New Zealand, Norway, and Sweden regarding dry milk

[5]Duties would be higher for countries that do not have normal trade relations; however, the United States does not import milk protein concentrates from any of these countries.

[6]Milk protein concentrates are classified in section 0404.90.10 of Chapter 4 of the *Harmonized Tariff Schedule of the United States, Annotated.*

[7]USDA's Food Safety and Inspection Service has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods.

[8]See *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (GAO/RCED-98-103, April 30,1998) for more details.

and milk protein imports. The agreements are to ensure that these countries adhere to FDA's food safety regulations, thereby minimizing the need for FDA to inspect these imports. No country has reached a broader agreement with the United States that their entire food safety system is equivalent to the United States thus enabling FDA to apply fewer resources to screening their imports. Dairy products, including milk protein concentrate products, will be subject to a not-yet-implemented "veterinary equivalency agreement" with the European Union and its 15 member countries. This agreement would provide a framework for the future equivalence of the European Union.

Ultra-filtered Milk Produced in the United States and Used in Standardized Cheeses

Many U.S. cheese plants produce and use wet ultra-filtered milk to make standardized and nonstandardized cheeses, according to industry executives. However, federal and industry sources could not provide data on the amount of wet ultra-filtered milk produced domestically or on its use. USDA and state officials told us that 22 dairy manufacturing plants nationwide and 4 large dairy farms in New Mexico and Texas have the capacity to make wet ultra-filtered milk. Most of the ultra-filtered milk is used within the dairy manufacturing plants to make cheese, although some is transported to other plants for use. The milk concentrated at on-farm ultra-filtration plants is transported mainly to cheese plants in the Midwest to make standardized cheese or other products.

Government and Industry Do Not Collect Data on Ultra-filtered Milk Production

Data are not routinely collected on the amount of ultra-filtered milk produced by U.S. cheese plants or other food processors for internal use or for shipment elsewhere, according to USDA and FDA officials and industry executives. USDA's Agricultural Marketing Service (AMS) staff, which oversees the administration of milk marketing in 11 regions across the United States, collects data on the intended use of the milk but not on intermediate products, such as ultra-filtered milk, that are often produced and used in making cheese. Similarly, AMS staff said that ultra-filtered milk produced in one plant for use in another is included with other bulk milk products and not tracked separately.

Trade association executives told us that they have no data on the amount of wet ultra-filtered milk U.S. dairy manufacturing plants produced and used. Trade association staff said that manufacturers would probably not respond to a request for such data because the information is considered proprietary and because of concern surrounding the petitions to use wet ultra-filtered milk now before FDA. Executives involved with the relatively

new on-farm production of ultra-filtered milk provided overall annual production data, which are discussed below.

Ultra Filtration of Milk Is Part of the Cheese-making Process in Many Plants

Many U.S. cheese-making plants have adopted ultra filtration of milk as part of the cheese-making process under the provisions in FDA's standards of identity regulations allowing for "alternate make" procedures for many of the standardized cheese and related cheese products. The "alternate make" procedures accommodate innovation by allowing these standardized cheeses to be made by any procedure that produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional process. Filtration removes the liquid components of milk that would otherwise be removed in the traditional process when whey is separated from cheese curd. Proponents of ultra filtration state that the cheese produced is also nutritionally equivalent. The goal of ultra-filtered milk producers is to create the ideal combination of milk solids (i.e., protein and fat) for the particular style of cheese.

AMS' milk marketing staff provided a list of milk processing plants that have ultra-filtration equipment for milk in the 47 states covered at least in part by federal milk market orders.[9] Three states—California, Alaska, and Hawaii—are not covered by federal regulation. We contacted officials in California—a large dairy state that regulates its dairy industry separately—to acquire similar information. The 48 states reported a combined total of 22 dairy manufacturing plants with ultra-filtration equipment for milk. AMS and California officials reported that at least five of these plants transported a portion of their ultra-filtered milk product to other plants. They further stated that it was possible for cheese makers to use their ultra-filtration equipment to concentrate the whey byproduct from the cheese-making process rather than to concentrate the milk entering the cheese-making process. AMS officials said that, to the extent they were aware, the transportation of ultra-filtered milk between manufacturing plants typically involved transfers between facilities of the same company.

The American Dairy Products Institute and the National Cheese Institute of the International Dairy Foods Association have petitioned FDA to amend its standards of identity for cheese to include wet ultra-filtered milk

[9]The federal milk market orders are a system of regulation administered by AMS that aims to benefit producers and consumers by establishing and maintaining orderly marketing conditions and assuring adequate supplies of milk.

in the definition of milk allowed in standardized cheese. According to the American Dairy Products Institute, ultra-filtration makes cheese manufacturing more efficient using new technology and may benefit consumers if cost savings are passed on. It also allows more efficient movement of milk from areas with an excess of fluid milk to areas with an insufficient supply, the American Dairy Products Institute said. The National Cheese Institute noted that the "alternate make procedure," already included in the regulations for some of the standardized cheeses, provides a legal basis for the use of filtered milk in the manufacture of standardized cheese. However, the institute wants to see the standards amended to explicitly recognize ultra-filtered milk in the standards' definition of milk. By explicitly recognizing ultra-filtered milk as milk for cheese manufacturing, FDA would allow manufacturers to use ultra-filtered milk in the standardized cheeses that do not include "alternate make procedure" provisions. The National Cheese Institute states that the greater use of ultra-filtered milk would help manage seasonal imbalances in the milk supply in various regions and in the demand for cheese. The institute said the lower hauling costs for filtered milk have enabled cheese makers to buy milk from distant regions and meet their needs for manufacturing, especially when regional milk supplies are disrupted by adverse conditions. FDA said it has exercised enforcement discretion on ultra-filtered milk, and has not enforced the standards of identity against cheese plants that use wet ultra-filtered milk produced outside of their plants.

On-Farm Ultra Filtration Opens Distant Markets to Southwestern Dairies

In 1996, T.C. Jacoby & Co., a St. Louis broker of dairy products, requested that FDA allow the use of ultra-filtered milk from an on-farm ultra-filtration plant in New Mexico to Bongards Creamery of Bongards, Minnesota, to make cheddar cheese. The broker also raised the issue of how to label the cheese to indicate the ultra-filtered milk ingredient in the final cheese product. FDA responded that the ultra-filtered milk could be used by Bongards to make cheddar cheese as long as the cheese was nutritionally, physically, and chemically the same as cheese produced traditionally. FDA allowed the label of the cheddar cheese to state that "milk" was an ingredient, provided that the cheddar cheese manufactured from it is equivalent. FDA allowed a pilot project for one farm and one cheese plant. The joint venture involving Jacoby & Co. subsequently expanded its production of ultra-filtered milk to three additional farms and its sales to manufacturers in Idaho, Illinois, Iowa, Minnesota, North Dakota, Ohio, Pennsylvania, South Dakota, and Wisconsin. FDA is considering the petitions but has taken no action to revise its standards of identity to reflect this use of ultra-filtered milk.

The joint venture's dairy, Select Milk Producers Inc., ultra-filters unheated whole raw milk on three farms in New Mexico and one in Texas. The process reduces the volume and weight of the whole milk the dairy starts with and reduces transportation costs for shipping it to manufacturers. The joint venture, which first sold wet ultra-filtered milk in 1997, reported sales of approximately 150 million pounds of ultra-filtered milk in 2000, mainly for making standardized cheeses.

On-farm ultra filtration of milk removes two-thirds of the liquid components of the milk—mainly water—to greatly reduce the costs to transport the ultra-filtered milk to market. For example, company officials noted one shipment for which the costs were reduced from $4.50 per hundredweight of milk to $1.20 for the remaining filtered milk. They added that this cost advantage is justified only for long-distance hauling, however, because the capital costs for installing ultra-filtration equipment are high. (See app. V for the composition of the various concentrates of wet ultra-filtered milk.)

FDA and State Entities Cooperate to Conduct a Limited Number of Cheese Plants Inspections

FDA relies on its own inspections and those conducted by the states under contract or partnership agreements to enforce its standards of identity regulations in about 1,000 cheese-making plants across the country. In fiscal year 1999, FDA inspected nine cheese-making plants for compliance with food labeling and economic regulations, which include checking compliance with the standards of identity for cheese. None of these inspections were done exclusively to monitor for compliance with standards of identity, and data indicating the number of these inspections that actually covered the standards of identity were not available. Similarly, the states conducting inspections on FDA's behalf did not exclusively inspect for the identity standards for cheese. In fiscal year 1999, FDA and state inspectors reported no violations for the use of imported ultra-filtered milk or milk protein concentrates to make standardized cheese. In addition, states conduct their own inspections of cheese plants for compliance with standards of identity requirements under state law. For example, in 2000, Vermont inspectors found two cheese plants using imported milk protein concentrates to make standardized cheeses in violation of federal and state regulations. Vermont issued warning letters and the plants discontinued this use.

FDA Performs Few Cheese Standards Inspections

FDA reported that its own inspections of cheese-making plants for compliance with FDA's food labeling and economic regulations, which include the standards of identity for cheese, are relatively infrequent. In

fact, they accounted for 9 of the total 499 domestic inspections for composition, standards, labeling, and economics regulations in all types of food manufacturing plants during fiscal year 1999. FDA said none of the nine inspections in cheese plants was done specifically to check for compliance with standards of identity on cheese. FDA also said that the agency devoted 0.7 staff year during fiscal year 1999 to FDA's food labeling and economic regulations for cheese.

However, FDA reported that its inspectors and state inspectors working for FDA in fiscal year 1999, inspected about 300 of approximately 1,000 cheese-making plants throughout the United States for a variety of other purposes. FDA inspected 108 plants on its own. FDA officials said that states inspected 65 cheese plants under partnership agreements, 125 cheese plants under 37 contracts, and 2 under both a state partnership and contract. Overall, FDA reported inspections of about 3,500 of about 22,000 food manufacturing plants in fiscal year 1999.

FDA and States Cooperate to Monitor Food Safety

To increase the number of inspections of food manufacturing firms, FDA has contracts or forms partnerships with state agencies to help carry out monitoring responsibilities relating to food safety and quality. FDA provides its compliance policies and inspection guidelines to state inspectors and sometimes conducts joint inspections with state inspectors. In addition, states such as Wisconsin and Vermont have adopted FDA's cheese standards of identity as their own standards under state law.

In fiscal year 2000, FDA had contracts with 37 states to cover food inspections. Under these contracts, FDA paid states to conduct and report on food inspections of all types. State officials then inspected locations under the state or FDA authority. The number of completed inspections to check for compliance with the standards of identity for cheese, however, was not available. Officials at Wisconsin's Department of Agriculture, Trade, and Consumer Protection told us they worked closely with FDA on contracted inspections, meeting annually with FDA officials to plan and coordinate their inspection efforts to avoid duplication. At these meetings, FDA provides state authorities with a list of the dairy establishments for Wisconsin inspectors to visit during the year. In addition, for each inspection done under its contract with FDA, Wisconsin inspectors complete a FDA inspection report describing the inspection results. Wisconsin officials reported that they did 82 inspections under the contract with FDA in fiscal year 1999 and 62 in fiscal year 2000.

Wisconsin officials told us that the state had 142 cheese-making plants in 1999 that produced many types of cheese. Wisconsin dairy inspectors check cheese plants for safety and sanitation, food composition and labeling regulations—including standards of identity—and to collect product samples. Wisconsin officials said their inspectors make on-site visits to cheese plants on a semiannual basis, taking a total of 36 samples each year for laboratory analysis of microbes, moisture content, and comparison of ingredients with FDA and Wisconsin standards. Wisconsin estimated that it expended 3.1 and 2.8 staff years in fiscal years 1999 and 2000 respectively, on routine inspections of cheese plants, not including nonroutine and contract inspections. State officials did not have the data to estimate the time spent specifically on standards of identity.

FDA and the states also have 15 partnership agreements related to FDA's regulation of dairy products. Under these partnerships, FDA and the states (or food-related organizations) collaborate on such efforts as training inspectors and sharing test results. FDA does not fund activities carried out by states under its partnership agreements, and the states bear the responsibility for handling any violations.

In addition to these efforts, the states conduct their own inspections under state law, which can include the standards of identity. For example, both Vermont and Wisconsin routinely inspect plants for compliance with state laws and regulations, and both have adopted FDA's standards of identity as part of their states' food safety and quality laws.

Vermont officials told us that the state has no formal working relationship, such as a partnership or a contract, with FDA relating to dairy inspections. However, Vermont's dairy inspectors coordinate with FDA on dairy matters. Vermont officials stated that about 2.0 staff years are used annually to inspect about 40 dairy plants, 28 of which are cheese making. Vermont's officials inspect the dairy plants for sanitation and cheese standards of identity and to collect samples. Tests of samples for microbes and animal drugs are done about once a month at the larger dairy plants. The inspectors visit the dairy plants on a quarterly basis and the larger plants about 20 times per year, according to Vermont officials.

FDA and the States Report Few Violations of Cheese Standards of Identity

FDA and the two states we contacted—Vermont and Wisconsin—report few violations of FDA's cheese standards of identity. In fiscal year 1999, FDA reported that no violations involving the use of ultra-filtered milk in standardized cheese in federal and the contracted state inspections. Likewise, Wisconsin officials told us that they had found no cheese

standards of identity violations relating to the use of ultra-filtered milk in cheese in the past few years. They did report a December 2000 incident in which a cheese plant was found to be using milk protein concentrate in nonstandardized ricotta cheese. While the use of the ingredient was not a violation of state or federal standards, the product's label did not identify the ingredient as required by law. The plant stopped using the milk protein concentrate until the label could be corrected, state officials reported.

In 2000, Vermont inspectors found two cheese plants using imported milk protein concentrate to make cheeses covered by FDA's standards of identity in violation of federal and state law. Vermont officials wrote letters to the plants warning that this ingredient was not permitted by the standards. Vermont officials said the plants discontinued its use and the cases were closed.

Agency Comments

We provided FDA with a draft of this report for its review and comment. FDA generally agreed with the report and provided some specific comments, which we have incorporated into the report as appropriate. FDA's comments and our responses are in appendix VI.

Scope and Methodology

To identify the trends in ultra-filtered milk imports into the United States between 1990 and 1999, we obtained data compiled by the U.S. Census Bureau from the U.S. Customs Service on annual imports of milk protein concentrates, which includes ultra-filtered milk. To identify any quantity, tariff, or other trade restrictions applicable to imported ultra-filtered milk, we reviewed the U.S. Harmonized Tariff Schedule and interviewed USDA, Customs, and FDA officials and representatives of domestic and foreign dairy trade associations and reviewed relevant reports and publications. To identify the uses of dry ultra-filtered milk and milk protein concentrates in the manufacture of cheese and other products in the United States, we obtained information from trade association representatives, domestic and foreign company executives, and federal officials.

To identify the use of domestically produced ultra-filtered milk in the manufacture of cheese and other food products in the United States, we reviewed relevant FDA standards of identity and other regulations and available published reports. We also interviewed USDA officials; California, Vermont, and Wisconsin state officials; trade association representatives; company executives; and academicians.

To identify FDA's and state agencies' efforts to enforce the federal standards of identity regulations, particularly the use of ultra-filtered milk in cheese production, we interviewed officials of USDA, FDA, Wisconsin, and Vermont regarding the extent of their activities and amount of staff resources used to monitor the standards. We conducted our review from August 2000 through February 2001 in accordance with generally accepted government auditing standards.

We are sending copies of this report to the congressional committees with jurisdiction over dairy products; the Honorable Ann M. Veneman, Secretary of Agriculture; the Honorable Dr. Bernard Schwetz, Acting Commissioner of the Food and Drug Administration; the Honorable Charles W. Winwood, Acting Commissioner, U.S. Customs Service; the Honorable Mitchell E. Daniels, Jr., Director of the Office of Management and Budget; and other interested parties. We will make copies available to others on request.

If you have any questions about this report, please contact me or Richard Cheston, Assistant Director, at (202) 512-3841. Key contributors to this report were Diana P. Cheng, Jonathan S. Murray, John P. Scott, and Richard B. Shargots.

Lawrence J. Dyckman
Director, Natural Resources
and Environment

List of Requesters

The Honorable Joe Skeen
House of Representatives

The Honorable David R. Obey
House of Representatives

The Honorable Tammy Baldwin
House of Representatives

The Honorable Russell D. Feingold
United States Senate

The Honorable James M. Jeffords
United States Senate

The Honorable Herb Kohl
United States Senate

Appendix I: Cheeses and Related Cheese Products Covered by FDA's Standards of Identity Regulations

Table 1 below shows the cheeses and related cheese products by section number covered by the Food and Drug Administration's (FDA) Standards of Identity regulations (21 C.F.R., Part 133, Subpart B). Because these regulations do not identify ultra-filtered milk as an approved ingredient, manufacturers of standardized cheeses and related cheese products cannot use ultra-filtered milk that is produced outside the cheese-making plant. (FDA has allowed an exception to this for a pilot project producing ultra-filtered milk on a farm in New Mexico for use in a Minnesota cheese plant.) If milk protein concentrates are used in a cheese product, then the product cannot bear the name of a standardized product, which is listed below. However, milk protein concentrates can be used as ingredients for nonstandardized cheese products not listed, such as feta cheese and pizza cheese. FDA also has standards of identity for many other product types, including milk and cream, frozen desserts, bakery, macaroni and noodles, and frozen vegetables.

Table 1: Cheeses and Related Cheese Products Covered by FDA's Standards of Identity Regulations

Section	Cheese
133.102	Asiago fresh and asiago soft cheese
133.103	Asiago medium cheese
133.104	Asiago old cheese
133.106	Blue cheese
133.108	Brick cheese
133.109	Brick cheese for manufacturing
133.111	Caciocavallo siciliano cheese
133.113	Cheddar cheese
133.114	Cheddar cheese for manufacturing
133.116	Low sodium cheddar cheese
133.118	Colby cheese
133.119	Colby cheese for manufacturing
133.121	Low sodium colby cheese
133.123	Cold-pack and club cheese
133.124	Cold-pack cheese food
133.125	Cold-pack cheese food with fruits, vegetables, or meats
133.127	Cook cheese, koch kaese
133.128	Cottage cheese
133.129	Dry curd cottage cheese
133.133	Cream cheese
133.134	Cream cheese with other foods
133.136	Washed curd and soaked curd cheese
133.137	Washed curd cheese for manufacturing
133.138	Edam cheese

Section	Cheese
133.140	Gammelost cheese
133.141	Gorgonzola cheese
133.142	Gouda cheese
133.144	Granular and stirred curd cheese
133.145	Granular cheese for manufacturing
133.146	Grated cheeses
133.147	Grated American cheese food
133.148	Hard grating cheeses
133.149	Gruyere cheese
133.150	Hard cheeses
133.152	Limburger cheese
133.153	Monterey cheese and Monterey jack cheese
133.154	High-moisture jack cheese
133.155	Mozzarella cheese and scamorza cheese
133.156	Low-moisture mozzarella and scamorza cheese
133.157	Part-skim mozzarella and scamorza cheese
133.158	Low-moisture part-skim mozzarella and scamorza cheese
133.160	Muenster and munster cheese
133.161	Muenster and munster cheese for manufacturing
133.162	Neufchatel cheese
133.164	Nuworld cheese
133.165	Parmesan and reggiano cheese
133.167	Pasteurized blended cheese
133.168	Pasteurized blended cheese with fruits, vegetables, or meats
133.169	Pasteurized process cheese
133.170	Pasteurized process cheese with fruits, vegetables, or meats
133.171	Pasteurized process pimento cheese
133.173	Pasteurized process cheese food
133.174	Pasteurized process cheese food with fruits, vegetables, or meats
133.175	Pasteurized cheese spread
133.176	Pasteurized cheese spread with fruits, vegetables, or meats
133.178	Pasteurized neufchatel cheese spread with other foods
133.179	Pasteurized process cheese spread
133.180	Pasteurized process cheese spread with fruits, vegetables, or meats
133.181	Provolone cheese
133.182	Soft ripened cheeses
133.183	Romano cheese
133.184	Roquefort cheese
133.185	Samsoe cheese
133.186	Sap sago cheese
133.187	Semisoft cheeses
133.188	Semisoft part-skim cheeses
133.189	Skim milk cheese for manufacturing
133.190	Spiced cheeses

Section	Cheese
133.191	Part-skim spiced cheeses
133.193	Spiced, flavored standardized cheeses
133.195	Swiss and emmentaler cheese
133.196	Swiss cheese for manufacturing

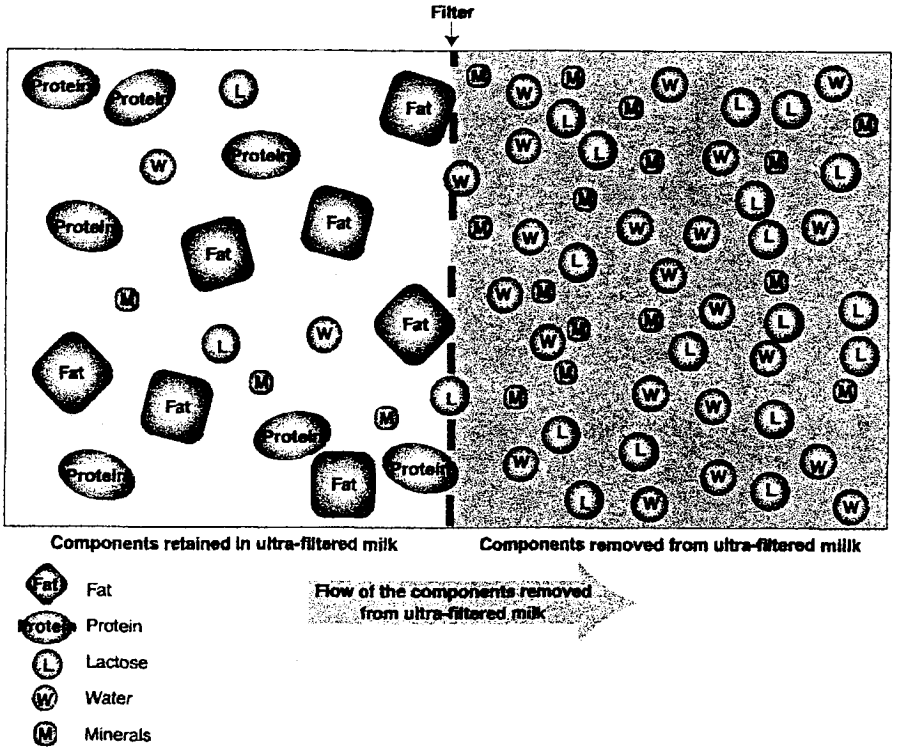
Appendix II: Use of Ultra Filtration in the Cheese-making Process

Cheese making combines an ancient art with scientific knowledge to manufacture uniform products by removing water and retaining the desirable solids in milk. Prior to making cheese, cheese makers test the quality of the milk. Then they may adjust for seasonal variations in the composition of milk, specifically milk proteins, to ensure that uniform milk is used to manufacture consistent cheese throughout the year. Traditionally, cheese makers use nonfat dry milk or liquid condensed milk as the chief ingredient to adjust the milk proteins but these have limitations due to the lactose content in these forms of milk. Ultra-filtered milk provides cheese makers with an alternative product for this purpose.

The Process of Ultra Filtration

Ultra-filtered milk concentrates the proteins by removing the water and lactose in milk, permitting greater efficiency in cheese making. Because the starting ingredients contain less liquid, the volume of whey (primarily water, lactose, whey proteins, and minerals) removed during cheese making is reduced and less effort and time are spent to expel the liquid from the cheese curds leading to its transformation into cheese. Figure 3 is a simplified diagram of the ultra-filtration process that enlarges a portion of the process to show how milk components are separated.

Figure 3: The Concept of Ultra Filtration



In ultra filtration, a filter (membrane with minute pores) retains the larger molecules (fat and protein) and allows the smaller molecules (water, lactose, and some minerals) to pass through. Although vitamins are a component in milk, they are not shown in the figure because they are found within the fat and water components.[1] Ultra filtration is not 100-percent efficient because some milk flows parallel to the filter pushed by pressure and not all of the milk comes in contact with the filter. Therefore, wet ultra-filtered milk will contain some water, lactose, and minerals.

Because of practical limitations on the amount of ultra-filtered milk that can be used in making cheese, ultra-filtered milk is normally used to supplement skim or whole milk used to make cheese. Cheese-making experts said that the majority of cheese vats in U.S. plants are not

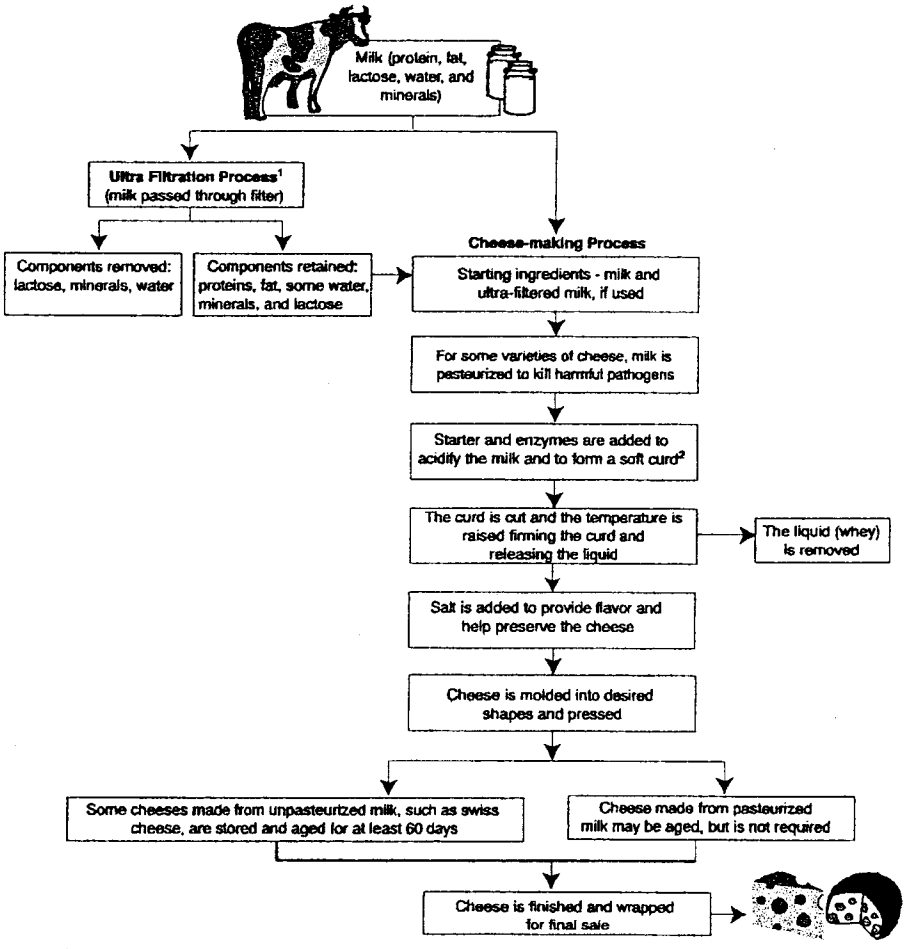
[1]Milk fat holds the fat-soluble vitamins (A, D, E, and K). The water-soluble vitamins are the B complex (i.e., riboflavin, thiamin, and niacin) and C vitamins.

designed to use only ultra-filtered milk, which is thicker than skim or whole milk. A high proportion of ultra-filtered milk would cause the equipment to malfunction. In addition, because highly concentrated ultra-filtered milk is not nutritionally equivalent to fluid milk, it could not be used as the sole ingredient in cheese. If cheese were made entirely from ultra-filtered milk, its texture, composition, and other characteristics would be different from cheese made traditionally. Although experts believe that these limitations can be addressed, the limitations currently prevent cheese makers from making cheese entirely from ultra-filtered milk at a concentration greater than "2X" in which half of the water is removed leaving twice as many solids (fat and protein) as compared to whole milk.

The Cheese-making Process

Figure 4 shows a flowchart of the cheese-making process. Ultra-filtered milk can be used to maintain consistent levels of fat and protein components in the raw milk used to make cheese, ensuring that cheese quality is the same throughout the year. It can also be used in larger quantities to increase the total solids (fat and proteins) in the raw milk, resulting in larger yields. Cheese making involves transforming milk proteins into solid lumps (curds), separating the curds' solids from the liquid (whey), shaping or pressing these curds into molds, and aging the shaped curds.

Figure 4: The Cheese-making Process



[1]Ultra-filtered milk can be used to supplement the fat and proteins in milk or to ensure that the components of milk for making cheese are consistent.

[2]Curds consist mainly of milk proteins that solidify in the process and become the foundation for the final cheese product.

Appendix III: U.S. Imports of Milk Protein Concentrates by Country, 1990-1999

Table 2 shows U.S. imports of milk protein concentrates between 1990 and 1999. Between 1990 and 1994, U.S. imports of milk protein concentrates increased 15-fold, and the number of suppliers grew from 4 countries to 11 countries. From 1995 to 1999, U.S. imports of milk protein concentrates increased 6-fold. Over the 10-year period, U.S. imports of milk protein concentrates increased 56-fold. Australia is the only country that exported milk protein concentrates to the United States in each year during this 10-year period.

Table 2: U.S. Imports of Milk Protein Concentrates by Country, 1990-1999

Quantity in metric tons										
	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
North America										
Canada	488	0	0	65	990	340	1,303	1,016	1,957	3,420
South America										
Argentina	0	0	0	0	0	218	163	36	0	0
European Union										
Sweden	45	0	1,171	3,491	3,492	722	703	663	39	98
Denmark	0	0	0	0	0	61	18	14	92	80
United Kingdom	0	0	422	0	369	0	20	0	19	66
Ireland	0	0	59	0	0	525	3,103	3,922	7,305	9,775
Netherlands	0	494	202	94	34	24	0	26	912	4,560
Belgium-Luxembourg	0	0	0	0	0	0	58	0	20	19
France	0	0	5	193	0	5	44	306	0	339
Germany	0	0	1,445	851	3,617	1,407	1,881	1,175	1,445	5,261
Austria	0	17	0	292	181	36	48	0	0	0
Spain	0	0	0	21	892	408	153	0	0	0
Italy	0	0	0	0	0	0	0	20	0	0
Other Western Europe										
Switzerland	0	0	0	0	0	0	0	0	0	52
Eastern Europe										
Hungary	17	0	369	0	170	153	162	168	395	416
Poland	0	0	20	470	331	237	700	519	2,720	875
Estonia	0	0	0	0	0	0	0	60	180	300
Lithuania	0	0	0	0	0	0	20	100	19	49
Africa										
Republic of South Africa	0	0	0	0	0	0	0	0	224	0
Asia										
Taiwan	0	0	0	0	0	0	0	0	112	0
Oceania										
Australia	255	238	85	342	455	152	1,036	1,141	2,246	4,967
New Zealand	0	373	158	0	1,477	3,000	4,905	7,831	11,243	14,601
Total	**805**	**1,122**	**3,936**	**5,819**	**12,008**	**7,288**	**14,317**	**16,997**	**28,928**	**44,878**

Note: One metric ton is equal to 2,204.6 pounds or 1,000 kilograms.

Source: Imports reported for classification number 0404.90.10 of the *Harmonized Tariff Schedule of the United States, Annotated,* as compiled by the U.S. Census Bureau from the U.S. Customs Service data.

Appendix IV: Types, Composition, and Suggested Uses of Dry Milk Protein Concentrates

Table 3 provides a general overview of the milk protein concentrate (MPC) products made from skim milk and their suggested uses, as provided by their distributors. It is not a comprehensive list because the uses for milk protein concentrate are reportedly expanding and developing, and only a few of the exporters we contacted opted to provide this information. Milk protein concentrates are typically described by their approximate protein content expressed as a percentage. For example, MPC 42 contains 42 percent protein based on dry weight. The other components in the product vary depending on its producer and customization of the products to meet customer specifications.

Table 3: Types, Composition, and Suggested Uses of Dry Milk Protein Concentrates

Product	Producer/distributor (MPC country of origin)	Composition[a] (percent)	Suggested uses[b]
MPC 42	Murray Goulburn Co-operative Co. Limited (Australia)	42.0 protein 2.0 fat 8.0 ash 45.5 lactose	Frozen deserts, nonfat dry milk replacement, bakery and confection applications, and cheese milk standardization.
	The Milky Whey, Inc. (Europe and New Zealand)	42.0 protein 1.0 fat 7.5 ash 45.5 lactose	
MPC 50	Murray Goulburn Co-operative Co. Limited (Australia)	49.8 protein 1.5 fat 8.0 ash 35.5 lactose	Frozen deserts, nonfat dry milk replacement, bakery and confection applications, and cheese milk standardization.
MPC 56	NZMP (North America) Inc. (New Zealand)	56.0 protein 1.2 fat 8.0 ash 31.0 lactose	Frozen deserts, nutritional beverage powders, bakery and confection applications, nonstandardized cheese products, and cheese milk standardization.
	Murray Goulburn Co-operative Co. Limited (Australia)	55.8 protein 1.5 fat 8.5 ash 30.5 lactose	
MPC 70	NZMP (North America) Inc. (New Zealand)	71.0 protein 1.0 fat 7.0 ash 17.0 lactose	Sports nutrition drinks and bars, aged care products, hospital rehabilitation products, and pasteurized process cheese products.
	Murray Goulburn Co-operative Co. Limited (Australia)	69.8 protein 2.0 fat 8.5 ash 15.5 lactose	
MPC 75	Murray Goulburn Co-operative Co. Limited (Australia)	74.8 protein 2.0 fat 8.5 ash 10.5 lactose	Sports nutrition drinks and bars, aged care products, and hospital rehabilitation products.

Product	Producer/distributor (MPC country of origin)	Composition[a] (percent)	Suggested uses[b]
MPC 80	Murray Goulburn Co-operative Co. Limited (Australia)	79.8 protein 2.5 fat 8.5 ash 5.5 lactose	Sports nutrition drinks and bars, aged care products, and hospital rehabilitation products.
MPC 85	Murray Goulburn Co-operative Co. Limited (Australia)	84.8 protein 2.5 fat 8.5 ash 0.5 lactose	Sports nutrition drinks and bars, aged care products, and hospital rehabilitation products.
MPC 90	NZMP (North America) Inc. (New Zealand)	86.7 protein 1.6 fat 7.1 ash 1.0 lactose	Products with a lactose- and sugar-free claim, nutritional foods, beverages, and frozen deserts.

Note: While the producers or distributors offer these MPC products, they did not state whether all are currently exported to the United States.

[a]The fat and ash levels listed are maximum levels; protein is listed at a minimum level; and lactose is given as an approximate value. Ash is an industry term for minerals, such as calcium and phosphorous.

[b]Producers stated that the exact uses for each product are dependent on the manufacturing processes and the characteristics of the protein and minerals contained in the particular MPC product.

Sources: Murray Goulburn Co-operative Co. Limited, Australia; NZMP (North America) Inc.; and The Milky Whey, Inc.

Appendix V: Types and Composition of Wet Ultra-filtered Milk

Table 4 provides the composition of various concentrations of wet ultra-filtered milk made from whole milk.[1] The composition of ultra-filtered milk depends on the composition of the raw milk, which may vary depending on the season in which the milk was produced.[2] Because ultra filtration removes liquids and concentrates the protein and fat components of milk, the table indicates the degree to which solids are concentrated. For example, in a "2X" concentration, half of the water is removed leaving twice as many solids (i.e. fat and protein) compared with whole milk.

Table 4: Types and Composition of Wet Ultra-filtered Milk

Concentration of ultra-filtered milk products	Composition of ultra-filtered whole milk products (percent)*
1.5X	4.48 protein 5.51 fat 0.95 ash 4.59 lactose
2 X	5.97 protein 7.34 fat 1.18 ash 4.41 lactose
2.5X	7.47 protein 9.18 fat 1.40 ash 4.23 lactose
3 X	8.96 protein 11.01 fat 1.63 ash 4.04 lactose
3.5X	10.45 protein 12.85 fat 1.86 ash 3.86 lactose
4 X	11.94 protein 14.68 fat 2.09 ash 3.68 lactose

*These percentages are based on the weight in the resulting concentrate.

Source: Northeast Dairy Foods Research Center, Cornell University.

[1]Ultra-filtered milk can also be made from skim milk.

[2]These calculations were made assuming the following whole milk composition (in percents): 2.9862 for true protein; 3.6700 for fat; 0.7159 for ash; and 4.7776 for lactose. True protein is the measurement of the protein content only and does not contain any non-protein nitrogen, which is of no value in making cheese.

Appendix VI: Comments From the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 16, 2001

Mr. Lawrence J. Dyckman
Director, Resources, Community,
and Economic Development Division
Food and Agricultural Issues
United States General Accounting Office
441 G Street, Northwest, Room 2T23
Washington, DC 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk (GAO-01-326).

Sincerely,

Theresa M. Mullin Ph.D., Director
Evaluation Staff
Office of Planning
Office of Policy, Planning, and Legislation

Enclosure

FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, DAIRY PRODUCTS: Imports, Domestic Production, and Regulation of Ultra-Filtered Milk GAO/01-326

The Food and Drug Administration (FDA) welcomes this report and appreciates the opportunity to review the General Accounting Office's (GAO) draft report, and provide comments. FDA generally agrees with the report and has the following general comments for consideration regarding this draft report.

GENERAL COMMENTS

See comment 1.

1. On Page 3, in the last paragraph, GAO implies that an "alternate make" procedure allows the use of alternate ingredients. That is not accurate. FDA suggests replacing the first sentence in its entirety with the following two sentences, "FDA standards of identity give cheese manufacturers permission under the "alternate make" provisions to use ultra-filtration as an acceptable procedure during the cheese making process. Consequently, milk that has been ultra-filtered as an integral part of the cheese making process has been acceptable as a component of a standardized cheese."

See comment 2.

2. In footnote 3 on page 4 and elsewhere in the draft document, GAO continues to use a percent of protein figure that FDA has identified to be incorrect. According to most sources in the literature on milk composition, the correct figure is on the order of 3.5 percent rather than GAO's current estimate of only 3 percent. The technical difference between the 3.5 percent number and the 3.0 percent number is inclusion of all nitrogen (a component of protein) in the 3.5 percent number and exclusion of nitrogen in the 3.0 percent number. Milk contains both protein and non-protein nitrogen. Thus, use of the 3.0 percent underestimates the protein level in milk products by approximately 16 percent. Using the 3.0 percent number will cause GAO's statistics to be wrong. If GAO calculates pounds of protein imported using the 3.5 percent number and compares it to domestic protein using the number 3.0 percent (page 4), the result is an "apples to oranges" comparison. The result is that the volume of imported protein expressed as a percentage of total U.S. production in 1999 will be artificially inflated. For the sake of complete accuracy, FDA strongly urges GAO to correct this error.

See comment 3.

3. Page 11, first paragraph, last sentence. Because FDA does not withhold enforcement, we exercise enforcement discretion, we offer the following suggestion: insert "exercise enforcement discretion" in place of "withhold enforcement".

GAO's Comments

The following are GAO's comments on the Food and Drug Administration's written response to our draft report dated February 2, 2001.

1. We have substituted these sentences as suggested.

2. We have added language to the footnote and to appendix V to explain that we are referring to the amount of "true" protein in whole milk, which is approximately 3 percent. While some sources in literature cite the higher value of "crude" protein, we feel "true" protein is the best value to use in our example. According to academic experts, the total or "crude" protein in milk that FDA refers to is estimated from measuring the total nitrogen content of milk. The total amount of nitrogen comes from both protein and non-protein sources. The experts noted that the measurement of "crude" protein is inaccurate because test equipment does not measure the amount of non-protein nitrogen precisely. By testing for "true" protein only, which electronic testing equipment can accurately detect, this measurement error is corrected. In addition, USDA's AMS, in its 1999 decision on milk market order reform, stated that the use of total or "crude" protein measurement overstates the amount of protein in milk by the amount of non-protein nitrogen, which has little or no effect on dairy product yields. Therefore, AMS decided that milk should be priced under federal milk orders on the basis of its true protein content.

3. We have revised the sentence as suggested.

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June 16, 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
HS 10-DIGIT IMPORTS

AREA/COUNTRIES OF ORIGIN AND COMMODITIES IMPORTED CONSUMPTION IMPORTS		JANUARY - DECEMBER QUANTITIES					JANUARY - APRIL COMPARISONS		
		2000	2001	2002	2003	2004	2004	2005	%CHNG
AUSTRALIA(*)	CASEN,XMPC,NESOI 3501105000 MT	5,248.0	4,898.4	6,415.3	8,763.0	7,267.8	2,647.2	1,933.1	-26.98
AUSTRIA	CASEN,XMPC,NESOI 3501105000 MT	0.0	106.9	0.0	0.0	0.0	0.0	0.0	–
BELGIUM-LUXEMBOURG(*)	CASEN,XMPC,NESOI 3501105000 MT	230.5	89.2	20.0	40.0	0.0	0.0	0.0	–
BELARUS	CASEN,XMPC,NESOI 3501105000 MT	0.0	118.5	125.5	82.5	60.0	60.0	40.6	-32.33
BULGARIA	CASEN,XMPC,NESOI 3501105000 MT	0.0	20.0	0.0	0.0	0.0	0.0	0.0	–
CANADA	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	–
CHINA, PEOPLES REPUB	CASEN,XMPC,NESOI 3501105000 MT	430.2	382.7	80.0	207.4	1,037.4	456.0	339.2	-25.61
DENMARK(*)	CASEN,XMPC,NESOI 3501105000 MT	17.5	168.1	18.6	0.0	0.0	0.0	0.0	–
IRELAND	CASEN,XMPC,NESOI 3501105000 MT	20,790.0	16,124.2	13,675.5	19,932.9	21,891.0	3,666.0	4,960.6	35.31
ESTONIA(*)	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	1.0	0.0	4.0	0.0	0.0	–
CZECH REPUBLIC	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	0.0	73.8	78.0	19.5	0.0	–
FRANCE(*)	CASEN,XMPC,NESOI 3501105000 MT	8,620.4	7,897.2	6,427.5	6,375.9	4,323.8	1,388.4	2,358.8	69.89
GERMANY(*)	CASEN,XMPC,NESOI 3501105000 MT	710.1	834.4	1,695.2	2,486.3	292.5	55.0	21.0	-61.82
HONG KONG	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	17.5	5.0	0.0	0.0	0.0	–
HUNGARY	CASEN,XMPC,NESOI 3501105000 MT	244.0	67.3	20.0	63.0	55.0	0.0	56.7	–
INDONESIA	CASEN,XMPC,NESOI 3501105000 MT	0.0	34.0	85.0	0.0	0.0	0.0	0.0	–
INDIA	CASEN,XMPC,NESOI 3501105000 MT	5,312.0	4,250.0	6,470.2	4,734.8	5,722.6	2,379.9	3,805.0	59.88
ITALY(*)	CASEN,XMPC,NESOI 3501105000 MT	59.2	24.6	24.8	24.5	0.0	0.0	0.0	–
KAZAKHSTAN, REPUBLIC	CASEN,XMPC,NESOI 3501105000 MT	100.0	0.0	30.7	20.0	0.0	0.0	0.0	–
LATVIA(*)	CASEN,XMPC,NESOI 3501105000 MT	40.0	100.0	160.0	140.0	20.0	20.0	0.0	–
LITHUANIA(*)	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	380.0	180.0	0.0	0.0	0.0	–
NETHERLANDS	CASEN,XMPC,NESOI 3501105000 MT	50.0	157.7	104.8	133.0	18.0	6.0	12.0	100.00
NORWAY(*)	CASEN,XMPC,NESOI 3501105000 MT	39.0	281.0	0.0	98.0	278.0	117.6	19.6	-83.33
NEW ZEALAND(*)	CASEN,XMPC,NESOI 3501105000 MT	23,969.1	21,829.0	16,983.8	21,446.4	22,351.4	7,937.7	11,647.6	46.74
POLAND	CASEN,XMPC,NESOI 3501105000 MT	309.0	587.8	273.4	891.4	130.0	101.2	0.0	–
PHILIPPINES	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	40.0	0.0	0.0	0.0	0.0	–
RUSSIAN FEDERATION	CASEN,XMPC,NESOI 3501105000 MT	4,695.6	1,729.0	2,341.2	1,022.7	91.8	11.8	0.0	–
TAIWAN	CASEN,XMPC,NESOI 3501105000 MT	0.0	0.0	0.0	0.0	20.0	0.0	0.0	–
UNITED KINGDOM	CASEN,XMPC,NESOI 3501105000 MT	607.4	20.0	0.0	860.1	1,799.2	679.2	540.0	-20.49
UKRAINE	CASEN,XMPC,NESOI 3501105000 MT	2,498.1	1,896.5	2,128.9	1,863.3	1,330.1	97.8	97.8	0.00
URUGUAY	CASEN,XMPC,NESOI 3501105000 MT	200.2	0.0	0.0	0.0	0.0	0.0	0.0	–
TOTAL	MT	74,170.2	61,616.6	57,519.1	69,444.0	66,770.5	19,643.2	25,832.1	31.51

Data Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics
Note: All zeroes for a data item may show that statistics exist in the other import type. Consumption or General.
(*) denotes a country that is a summarization of its component countries.

**** WARNING ****

Users should use cautious interpretation on QUANTITY reports using mixed units of measure. Commodity groups on a value report will reflect a total of all statistics for each commodity in the group in DOLLARS, whereas a QUANTITY line item will show statistics on the greatest number of like units of measure for grouped commodities.

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June 15, 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
ECONOMIC RESEARCH SERVICE
FATUS IMPORT AGGREGATIONS

AREA/COUNTRIES OF ORIGIN AND COMMODITIES IMPORTED GENERAL IMPORTS			JANUARY - DECEMBER QUANTITIES					JANUARY - APRIL COMPARISONS		
			2000	2001	2002	2003	2004	2004	2005	%CHNG
ARGENTINA	CASEIN AND MIXTURES	MT	10.2	0.0	0.0	0.0	0.0	0.0	0.0	–
AUSTRALIA(*)	CASEIN AND MIXTURES	MT	5,407.1	5,015.3	7,867.8	14,340.1	12,290.6	4,589.7	3,595.4	-21.66
AUSTRIA	CASEIN AND MIXTURES	MT	0.0	152.1	0.0	0.0	0.0	0.0	0.0	–
BELGIUM-LUXEMBOURG(*)	CASEIN AND MIXTURES	MT	269.9	89.2	20.0	40.0	0.0	0.0	0.0	–
BELARUS	CASEIN AND MIXTURES	MT	20.0	118.5	225.8	162.4	120.0	100.0	40.6	-59.40
BULGARIA	CASEIN AND MIXTURES	MT	0.0	20.0	0.0	0.0	0.0	0.0	0.0	–
CANADA	CASEIN AND MIXTURES	MT	0.0	20.7	15.3	0.0	25.3	0.8	20.0	2400.00
CHINA, PEOPLES REPUB	CASEIN AND MIXTURES	MT	430.4	392.2	200.3	565.6	1,434.8	617.1	482.1	-21.88
COSTA RICA	CASEIN AND MIXTURES	MT	4.8	0.0	0.0	5.0	8.1	0.0	0.0	–
DENMARK(*)	CASEIN AND MIXTURES	MT	2,131.0	2,064.0	1,804.4	2,605.0	2,175.7	745.2	546.9	-26.61
DOMINICAN REPUBLIC	CASEIN AND MIXTURES	MT	0.9	0.0	0.0	0.0	0.0	0.0	0.0	–
IRELAND	CASEIN AND MIXTURES	MT	24,328.2	20,470.3	20,095.4	22,551.0	22,446.0	4,166.8	5,450.5	30.81
ESTONIA(*)	CASEIN AND MIXTURES	MT	500.0	200.0	1.0	434.0	10.5	0.0	0.0	–
EL SALVADOR	CASEIN AND MIXTURES	MT	1.0	0.0	0.0	0.0	0.0	0.0	0.0	–
CZECH REPUBLIC	CASEIN AND MIXTURES	MT	0.0	0.0	0.0	273.4	78.0	19.5	0.0	–
FRANCE(*)	CASEIN AND MIXTURES	MT	14,586.0	9,731.2	8,329.4	8,293.5	10,741.5	3,039.8	3,641.7	19.80
GERMANY(*)	CASEIN AND MIXTURES	MT	6,616.6	6,596.6	6,582.7	9,017.0	5,276.7	2,061.4	921.1	-55.32
HONG KONG	CASEIN AND MIXTURES	MT	0.0	0.0	17.5	5.0	0.0	0.0	0.0	–
HUNGARY	CASEIN AND MIXTURES	MT	666.6	346.8	219.4	565.9	268.9	88.4	56.7	-35.86
INDONESIA	CASEIN AND MIXTURES	MT	0.0	34.0	85.0	0.0	0.0	0.0	0.0	–
INDIA	CASEIN AND MIXTURES	MT	5,336.0	4,351.1	6,490.2	4,809.8	5,753.0	2,410.3	4,271.0	77.20
ITALY(*)	CASEIN AND MIXTURES	MT	59.2	24.6	24.8	24.5	0.0	0.0	0.0	–
JAPAN	CASEIN AND MIXTURES	MT	35.2	0.0	0.0	0.0	12.2	0.0	0.0	–
KAZAKHSTAN, REPUBLIC	CASEIN AND MIXTURES	MT	100.0	0.0	30.7	20.0	0.0	0.0	0.0	–
LATVIA(*)	CASEIN AND MIXTURES	MT	40.0	100.0	160.0	200.8	80.0	80.0	0.0	–
LITHUANIA(*)	CASEIN AND MIXTURES	MT	17.0	0.0	380.0	180.0	0.0	0.0	0.0	–
MEXICO	CASEIN AND MIXTURES	MT	0.0	0.0	0.0	11.0	80.5	11.3	19.2	69.91
NIGER	CASEIN AND MIXTURES	MT	1.0	0.0	0.0	0.0	0.0	0.0	0.0	–
NETHERLANDS	CASEIN AND MIXTURES	MT	7,503.7	7,396.5	7,352.7	8,152.1	9,066.9	3,395.3	3,292.5	-3.03
NORWAY(*)	CASEIN AND MIXTURES	MT	39.0	281.0	0.0	137.1	278.0	117.6	19.6	-83.33
NEW ZEALAND(*)	CASEIN AND MIXTURES	MT	40,226.6	40,721.2	31,636.1	35,785.4	33,121.9	11,414.1	17,547.9	53.74
POLAND	CASEIN AND MIXTURES	MT	973.5	3,631.2	2,941.3	4,585.7	4,947.8	1,281.8	1,215.1	-5.20
PHILIPPINES	CASEIN AND MIXTURES	MT	0.0	0.0	40.0	0.0	0.0	0.0	0.0	–
RUSSIAN FEDERATION	CASEIN AND MIXTURES	MT	4,783.6	1,753.0	2,361.2	1,042.7	91.8	11.8	0.0	–
SOUTH AFRICA, REPUBL	CASEIN AND MIXTURES	MT	0.0	0.0	0.1	0.0	0.0	0.0	0.0	–
SPAIN	CASEIN AND MIXTURES	MT	100.0	0.0	40.0	0.0	0.0	0.0	0.0	–
SWITZERLAND(*)	CASEIN AND MIXTURES	MT	44.6	0.0	5.4	0.0	193.5	1.6	171.0	10587.50
TAIWAN	CASEIN AND MIXTURES	MT	0.0	0.0	0.0	6.6	20.0	0.0	0.0	–
UNITED KINGDOM	CASEIN AND MIXTURES	MT	2,994.0	1,160.3	1,055.4	1,372.5	1,821.5	679.2	540.0	-20.49
UKRAINE	CASEIN AND MIXTURES	MT	2,552.1	2,095.0	2,128.9	1,883.6	2,646.5	299.7	237.8	-20.65
URUGUAY	CASEIN AND MIXTURES	MT	200.2	0.0	0.0	0.0	0.0	0.0	0.0	–

Data Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics
(*) denotes a country that is a summarization of its component countries.

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June 15, 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
FAS AGRICULTURAL IMPORT COMMODITY AGGREGATIONS

AREA/COUNTRIES OF ORIGIN AND COMMODITIES IMPORTED GENERAL IMPORTS			APRIL - MARCH QUANTITIES					APRIL - APRIL COMPARISONS		
			2001	2002	2003	2004	2005	2004	2005	%CHNG
AUSTRALIA(*)	CASEIN	MT	4,840.3	5,346.8	7,564.4	7,533.6	7,233.5	935.9	279.6	-70.13
AUSTRIA	CASEIN	MT	0.0	152.1	0.0	0.0	0.0	0.0	0.0	–
BELGIUM-LUXEMBOURG(*)	CASEIN	MT	167.3	74.5	20.0	40.0	0.0	0.0	0.0	–
BELARUS	CASEIN	MT	40.0	78.5	145.4	102.5	40.0	20.0	40.6	103.00
BULGARIA	CASEIN	MT	0.0	20.0	0.0	0.0	0.0	0.0	0.0	–
CANADA	CASEIN	MT	0.0	20.7	0.0	0.8	4.5	0.0	0.0	–
CHINA, PEOPLES REPUB	CASEIN	MT	537.4	252.6	241.1	825.5	1,271.0	232.1	222.9	-3.96
COSTA RICA	CASEIN	MT	4.8	0.0	5.0	0.0	8.1	0.0	0.0	–
DENMARK(*)	CASEIN	MT	1,458.1	1,766.7	1,744.6	2,615.4	2,072.8	247.6	120.4	-51.37
DOMINICAN REPUBLIC	CASEIN	MT	0.9	0.0	0.0	0.0	0.0	0.0	0.0	–
IRELAND	CASEIN	MT	21,216.9	21,194.9	18,409.1	20,807.4	23,119.2	1,599.0	1,698.0	6.19
ESTONIA(*)	CASEIN	MT	0.0	0.0	1.0	0.0	4.0	0.0	0.0	–
EL SALVADOR	CASEIN	MT	1.0	0.0	0.0	0.0	0.0	0.0	0.0	–
CZECH REPUBLIC	CASEIN	MT	0.0	0.0	0.0	292.9	58.5	0.0	0.0	–
FRANCE(*)	CASEIN	MT	12,679.6	9,372.5	7,850.5	7,230.7	8,604.7	866.4	1,103.6	27.38
GERMANY(*)	CASEIN	MT	6,843.7	6,046.0	6,978.5	8,285.2	4,377.3	499.1	214.6	-57.00
HONG KONG	CASEIN	MT	0.0	17.5	0.0	5.0	0.0	0.0	0.0	–
HUNGARY	CASEIN	MT	239.7	67.3	20.0	63.0	151.7	0.0	0.0	–
INDONESIA	CASEIN	MT	0.0	34.0	85.0	0.0	0.0	0.0	0.0	–
INDIA	CASEIN	MT	5,495.8	5,029.5	7,119.6	3,805.0	7,374.2	576.0	815.5	41.58
ITALY(*)	CASEIN	MT	59.2	24.6	37.0	12.4	0.0	0.0	0.0	–
JAPAN	CASEIN	MT	7.3	0.0	0.0	0.0	12.2	0.0	0.0	–
KAZAKHSTAN, REPUBLIC	CASEIN	MT	100.0	30.7	0.0	20.0	0.0	0.0	0.0	–
LATVIA(*)	CASEIN	MT	80.0	120.0	120.0	140.0	0.0	0.0	0.0	–
LITHUANIA(*)	CASEIN	MT	0.0	0.0	380.0	180.0	0.0	0.0	0.0	–
MEXICO	CASEIN	MT	0.0	0.0	0.0	22.3	88.5	0.0	0.0	–
NIGER	CASEIN	MT	1.0	0.0	0.0	0.0	0.0	0.0	0.0	–
NETHERLANDS	CASEIN	MT	7,475.7	7,473.1	7,483.2	8,451.4	8,967.6	707.9	704.5	-0.48
NORWAY(*)	CASEIN	MT	129.8	151.2	0.0	235.2	180.0	0.0	0.0	–
NEW ZEALAND(*)	CASEIN	MT	33,857.1	32,241.5	33,104.2	33,324.0	33,049.8	891.4	3,904.4	338.01
POLAND	CASEIN	MT	1,303.8	3,637.7	3,126.8	4,103.5	4,535.6	367.8	469.0	27.51
PHILIPPINES	CASEIN	MT	0.0	0.0	40.0	0.0	0.0	0.0	0.0	–
RUSSIAN FEDERATION	CASEIN	MT	4,528.6	1,842.4	2,467.0	455.5	80.0	0.0	0.0	–
SOUTH AFRICA, REPUBL	CASEIN	MT	0.0	0.0	0.1	0.0	0.0	0.0	0.0	–
SPAIN	CASEIN	MT	0.0	0.0	40.0	0.0	0.0	0.0	0.0	–
SWITZERLAND(*)	CASEIN	MT	0.1	0.0	0.0	0.0	0.0	0.0	0.0	–
TAIWAN	CASEIN	MT	0.0	0.0	0.0	6.6	20.0	0.0	0.0	–
UNITED KINGDOM	CASEIN	MT	617.6	29.5	25.4	1,530.1	1,562.4	100.0	220.0	120.00
UKRAINE	CASEIN	MT	2,212.1	2,219.0	2,069.3	1,723.0	2,230.3	97.8	60.0	-38.65
URUGUAY	CASEIN	MT	200.2	0.0	0.0	0.0	0.0	0.0	0.0	–
TOTAL		MT	104,098.0	97,243.5	99,077.3	101,810.9	105,045.7	7,141.2	9,853.1	37.98

Data Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics
Note: All zeroes for a data item may show that statistics exist in the other import type. Consumption or General.
(*) denotes a country that is a summarization of its component countries.

**** WARNING ****

Users should use cautious interpretation on QUANTITY reports using mixed units of measure. Commodity groups on a value report will reflect a total of all statistics for each commodity in the group in DOLLARS, whereas a QUANTITY line item will show statistics on the greatest number of like units of measure for grouped commodities.

(10)

HR 4223 IH

108th CONGRESS

2d Session

H. R. 4223

To require the Commodity Credit Corporation to support the development of a domestic casein and milk protein concentrate industry, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

April 27, 2004

Mr. NUNES (for himself, Mr. SHERWOOD, Mr. GREEN of Wisconsin, Mr. CARDOZA, Mr. POMBO, Mr. MCCOTTER, Mr. RADANOVICH, Mr. MARIO DIAZ-BALART of Florida, Mr. PEARCE, Mr. SIMPSON, Mr. PETERSON of Minnesota, and Mr. LATOURETTE) introduced the following bill; which was referred to the Committee on Agriculture

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A BILL

To require the Commodity Credit Corporation to support the development of a domestic casein and milk protein concentrate industry, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. UNITED STATES DAIRY PROTEINS INCENTIVE PROGRAM.

(a) Establishment and Purpose- The Commodity Credit Corporation shall establish and operate a program under section 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714c) to support the development of a casein and milk protein concentrate industry in the 48 contiguous States.

(b) Program Described- Under the program, the Corporation shall make payments, on a bid basis, to an entity that produces and markets dairy proteins produced from liquid skim milk. The Secretary of Agriculture shall have sole discretion to accept or reject bids under such criteria as the Secretary considers appropriate.

(c) Rules and Regulations- The program shall be operated under such rules and regulations issued by the Secretary as the Secretary considers necessary to ensure, among other things, that--

(1) receipt of a payment is contingent upon the end use of the dairy proteins produced;

(2) no applicant receives a payment if the contract submitted for review would result in the undercutting of domestic prices for milk, nonfat dry milk, or dairy proteins; and

(3) the sale of the dairy proteins represents a new use of the domestically produced dairy proteins.

(d) Cheese Products Exception- The sale of dairy proteins for use in the production of standardized cheeses, as determined by the Secretary, shall not be eligible to receive payments under the program.

(e) Payment Rate- Payments made under the program shall be made at a rate or rates established or approved by the Secretary. Any such rate shall be published in the Federal Register or publicly announced through other appropriate means, and shall be at a level or levels that will encourage the development of a dairy proteins industry in the 48 contiguous States.

(f) Implementation of Program- The Secretary shall develop regulations and implement the program *not later than 180 days after the date of the enactment of this section.*

(g) Treaty Obligations- The Secretary shall carry out the program in a manner consistent with the obligations of the United States as a member of the World Trade Organization.

(h) Dairy Protein Definition- In this section, the term `dairy proteins' means whey, whey protein concentrate, casein, or milk protein concentrate.

END

U.S. A "Milk-Deficiet Nation" Since 1996

	U.S. Production	Commercial Disappearance	Difference	All Milk price
1990	147,720	138,838	8,882	13.68
1991	147,696	138,601	9,095	12.24
1992	150,847	141,307	9,540	13.09
1993	150,636	145,486	5,150	12.80
1994	153,602	150,307	3,295	12.97
1995	155,292	154,733	559	12.74
1996	154,006	154,750	-744	14.88
1997	156,091	156,118	-27	13.34
1998	157,262	159,721	-2,459	15.50
1999	162,589	164,823	-2,234	14.35
2000	167,393	168,963	-1,570	12.31
2001	165,332	169,493	-4,161	14.97
2002	170,063	170,872	-809	12.11
2003	170,312	174,633	-4,321	12.53
2004	170,805	176,278	-5,473	16.05

Source: USDA-ERS. Volumes in million pounds. Price in dollars/cwt.

Since 1996, dairy product demand has exceeded farm milk production. "Supply-demand" does not drive milk prices. Imports have a huge negative impact lowering farm milk prices.